UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

In re ZETIA (EZETIMIBE)
ANTITRUST LITIGATION

CIVIL ACTION NO. 2:18-md-2836

THIS DOCUMENT RELATES TO:
All cases

MAGISTRATE JUDGE'S REPORT AND RECOMMENDATION

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Introduction

In this multidistrict antitrust litigation, Plaintiffs allege that Defendants illegally conspired to artificially inflate the price of prescription drugs. The Complaints principally arise out of a patent infringement settlement concerning the drug ezetimibe, the active ingredient in the branded cholesterol-control medication Zetia. Plaintiffs allege that as part of their settlement, the brand manufacturer defendants made an unlawful "reverse payment" in exchange for the generic manufacturer's delayed entry into the market. Plaintiffs claim that this quid pro quo agreement is subject to antitrust scrutiny under the Supreme Court's decision in FTC v. Actavis, 570 U.S. 136 (2013). Plaintiffs assert claims under the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2, along with antitrust and other claims under the laws of thirty-eight states, the District of Columbia, and Puerto Rico.

The matter is now before the court on three separate Motions to Dismiss all claims, each directed at one of the three classes of plaintiffs in the case.[1] Defendants argue that Plaintiffs have failed to plausibly allege any payment or other agreement that

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[1] See explanation of plaintiff classes, infra. The three motions, as docketed in the consolidated MDL (Case No. 2:18md2836), are ECF No. 157 (Direct Purchaser Plaintiffs); ECF No. 160 (Retailer Plaintiffs); and ECF No. 162 (End Payor Plaintiffs).

would give rise to antitrust liability under federal law. They also assert that plaintiffs proceeding under state law either lack standing or have failed to state a claim for various reasons particular to those claims.

Pursuant to 28 U.S.C. §636(b)(1)(B) and Federal Rule of Civil Procedure 72(b), the assigned district judge referred the motions to the undersigned for a report and recommendation. The court heard oral argument on all the motions January 14, 2019. As explained in greater detail below, this Report concludes that Plaintiffs have stated claims under both Sherman Act counts. Such claims are analyzed under the rule of reason approach set out by the Supreme Court in Actavis. There is, however, no per se violation of antitrust law arising from the same conduct. The count asserting a per se violation alleged only by the Retailer Plaintiffs fails to state a claim and should be dismissed. The Report also concludes the named End Payor Plaintiffs have standing to pursue the claims they assert, and any challenge to claims they assert in a representative capacity should be addressed at the class certification stage under Rule 23.

Finally, while some of the state antitrust, consumer protection, and unjust enrichment claims are adequately pled, the Report concludes that several are barred by the law of the states which created the remedies sought to be enforced here.

Accordingly, as set out below, this Report recommends the Motions to Dismiss be GRANTED IN PART and DENIED IN PART.

I. Parties and Claims

A. Defendants

Merck & Company, Inc. is a New Jersey corporation that through itself and its subsidiaries markets and sells Zetia throughout the United States. Direct Purchaser Plaintiffs' Consolidated Class Action Complaint ("DPP Compl.") ¶ 10 (ECF No. 128 at 9). In 2009, Merck & Company, Inc. merged into defendant Schering-Plough Corporation and the resulting entity changing its name to Merck & Company, Inc. DPP Compl. ¶ 14. The original Merck & Company, Inc. changed its name to Merck Sharp & Dohme Corporation, another named defendant. DPP Compl. ¶ 14. Schering Corporation was a wholly owned subsidiary of Schering-Plough corporation and the original assignee of the relevant patents in this matter. DPP Compl. ¶ 13. Those patents are now assigned to defendant Merck Sharp & Dohme Corporation. DPP Compl. ¶ 11. MSP Singapore Company LLC ("MSP") is a subsidiary of Merck & Company, Inc.; it held the New Drug Application ("NDA") for ezetimibe and was the exclusive licensee of the relevant patents. DPP Compl. ¶ 15; Br. Supp. Defs' Mot. Dismiss DPP Compl. 2 n.1 (ECF No. 158 at 7 n.1). Except where otherwise indicated, all these Merck Defendants will be collectively referred to in this Report as "Merck."

Glenmark Pharmaceuticals Limited is a foreign company, which, along with its wholly owned subsidiary Glenmark Pharmaceuticals Inc., USA, will be collectively referred to in this Report as "Glenmark."[2] Glenmark is a generic drug manufacturer which, on October 25, 2006, filed the first Abbreviated New Drug Application seeking FDA approval for its generic version of Zetia. DPP Compl. ¶ 146. After Merck sued Glenmark for patent infringement, the two companies entered into the Settlement Agreement that is the core subject matter of this litigation.

B. Plaintiffs

Plaintiffs are corporations or other entities that allegedly purchased brand-name and generic Zetia at supracompetitive prices from late 2011 until at least June 12, 2017. DPP Compl. 84-85. Plaintiffs are divided into three groups. The Direct Purchaser Plaintiffs ("DPPs") are drug wholesalers that purchased brand-name and generic Zetia directly from the Defendants.[3] The DPPs assert

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[2] According to Defendants, Plaintiffs incorrectly identified Glenmark Pharmaceuticals Inc., USA as "Glenmark Generics Inc., USA" in their Complaints. Br. Supp. Mot. Dismiss EPP Compl. 1 (ECF No. 163 at 1).

[3] The named class representatives for the DPPs are FWK Holdings, LLC; Rochester Drug Cooperative, Inc.; and Cesar Castillo, Inc. DPP Compl. 3-4.

federal antitrust claims on behalf of themselves and similarly situated class members under 15 U.S.C. §§ 1 & 2.

The Retailer Plaintiffs CVS, Walgreens, and Rite Aid ("Retailers") are large pharmacy retailers which assert claims on their own behalf and as assignees of claims from pharmaceutical wholesalers which purchased Zetia directly from Merck for resale to Retailers. Retailers assert three federal antitrust claims: (1) per se violation of 15 U.S.C. § 1; (2) violation of § 1 under rule of reason analysis; and (3) violation of § 2. Although the retailers are also direct purchasers, they are pursuing their claims individually and do not seek class certification.

The End Payor Plaintiffs ("EPPs") are a collection of municipal corporations, employee welfare benefit plans, or other similar entities. The EPPs allege that they purchased and/or provided reimbursement for purchases of Zetia and its generic equivalents for members or plan beneficiaries at supracompetitive prices.[4] Because the EPPs were downstream buyers who did not

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[4] The named class representatives for the EPPs are the Sergeants Benevolent Association Health & Welfare Fund; United Food and Commercial Workers Local 1500 Welfare Fund; Philadelphia Federation of Teachers Health & Welfare Fund; Self-Insured Schools of California; City of Providence, Rhode Island; Law Enforcement Health Benefits, Inc.; Painters District Council No. 30 Health & Welfare Fund; International Union of Operating Engineers Local 49 Health & Welfare Fund; Turlock Irrigation District; Uniformed Firefighters' Association of Greater New York Security Benefit

purchase Zetia directly from Defendants, they allege only indirect injury caused by Defendants' conduct. End Payor Consol. Class Action Compl. 80-81 (ECF No. 130 at 85-86). On their own behalf, and for similarly situated class members, the EPPs bring four sets of claims: (1) conspiracy and combination in restraint of trade under the antitrust laws of twenty-six states, the District of Columbia, and Puerto Rico; (2) analogous state-law monopolization claims in those same jurisdictions; (3) consumer protection claims under the laws of twenty-seven states and the District of Columbia; and (4) unjust enrichment claims under the laws of thirty-seven states and the District of Columbia.

II. Regulatory Background

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), pharmaceutical companies must obtain approval from the Food and Drug Administration ("FDA") before marketing new drugs. 21 U.S.C. § 355. A company seeking approval files a New Drug Application ("NDA"), which must include information about the safety and efficacy of the drug, the drug's components, how the drug is made and packaged, and any patents on the drug's ingredients or methods

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Fund; and the Retired Firefighters' Security Benefit Fund of the Uniformed Firefighters' Association of Greater New York Security Benefit Fund; and United Food and Commercial Workers Local 1500 Welfare Fund.

of use. Id. § 355(b). The process of compiling an NDA, which requires comprehensive clinical testing (subject to its own approval processes) is long and expensive.

Once the FDA approves a manufacturer's NDA, the manufacturer may list it in the directory of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Id. § 355(b)(1). The Orange Book listing contains any patents that the manufacturer believes it could assert against a generic manufacturer that makes, uses, or sells a generic version of the drug. Id. Certain NDAs qualify for New Chemical Entity ("NCE") exclusivity, which bars the FDA from accepting for review any ANDA referencing the NDA for a period of five years (or four in certain circumstances). Id. § 355(c)(3)(E)(ii).

A. Hatch-Waxman Amendments and Generic Drug Approval

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Act simplified the regulatory process that generic drug manufacturers must traverse to bring generic drugs to market. Under the Hatch-Waxman Act, generic manufacturers may file an Abbreviated New Drug Application ("ANDA") in lieu of a full NDA. An ANDA allows the generic manufacturer to "piggy-back on the pioneer's approval efforts" in order to come to market quicker and with less expense. Actavis, 570 U.S. at 142. ANDAs may rely on the safety and effectiveness

findings in the listed drug's NDA by specifying that the generic is "bioequivalent" to the listed drug—that it contains the same active ingredient and exhibits the same "bioavailability." Id. (citing 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iv)).

Because generic manufacturers can submit ANDAs before the patent terms covering brand drugs expire, they must also certify that the generic drug will not infringe any patents listed in the Orange Book. Id. at 143 (citation omitted). Generic manufacturers may submit one of four types of certifications: (I) that the Orange Book does not list any patents covering the brand drug; (II) that any listed patents are expired; (III) that the generic is not seeking approval until the date any listed patents expire; or (IV) that any listed patent is invalid, unenforceable, or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). The fourth option is commonly referred to as "paragraph IV certification." In re Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 711 (N.D. Ill. 2016). Paragraph IV ANDAs may be filed four years after approval of an NDA which receives NCE exclusivity. 21 U.S.C. Id. § 355(j)(5)(F)(ii).

A generic manufacturer filing an ANDA with a paragraph IV certification must notify the patent holder of the filing. § 355(j)(2)(B). Although no competing generic has yet been manufactured, submission of a paragraph IV certification ANDA automatically triggers a claim for patent infringement. 35 U.S.C.

§ 274(e)(2)(A). If a brand manufacturer files a patent infringement suit against the generic ANDA filer within 45 days of receiving notice, it results in an automatic 30-month stay, during which the FDA may not approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). But if during that 30-month period the parties litigate the infringement suit to a final judgement or settlement which declares the patent invalid or not infringed, then the FDA may approve the ANDA prior to expiration of the 30 months. Id.

B. Generic Drug Exclusivity

To incentivize generic drug development and market entry, as well as challenges to potentially suspect patents listed in the Orange Book, the Hatch-Waxman Act permits the first company to file a paragraph IV ANDA (a "first-filer") a 180-day period of generic marketing exclusivity. § 355(j)(5)(B)(iv). During this 180 days the FDA may not approve a later-filed ANDA referencing the same listed brand drug. Only the brand drug manufacturer is permitted to market a competing generic (a so-called "Authorized Generic" or "AG") during this time; all other generic manufacturers must await expiration of the exclusivity window.

The 180-day exclusivity period can be extremely valuable for the first-filer. Generic manufacturers reap most of their potential profits during this time, which can be hundreds of millions of dollars. See Actavis, 570 U.S. at 144. Generic drug market entry is aided by state laws permitting, and in many cases

requiring, pharmacies to substitute therapeutically equivalent generic drugs for brand drugs absent a physician's contrary instructions. See Opana, 162 F. Supp. 3d at 712. As a result, generics can quickly capture a large portion of the market for the corresponding branded drug. See id.; DPP Compl. ¶¶ 51-55.

C. "Reverse Payment" Patent Settlements and the Actavis Decision

The regulatory framework above gives generic manufacturers strong incentive to bring paragraph IV challenges to seemingly vulnerable patents. And brand manufacturers, faced with the prospect of losing their exclusivity, have good reason to respond with infringement suits against those companies. Given the expense of patent infringement litigation, however, brand manufacturers may seek to settle such claims, particularly if they "suspect their challenged patents may indeed be vulnerable." In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 234 (D. Conn. 2015). Such settlements sometimes result in the plaintiff (the patent holder) paying the defendant (the generic manufacturer and accused infringer). This type of settlement is commonly called a "reverse payment" settlement agreement. See id.; see also Actavis, 570 U.S. at 155-56 (noting that "reverse payment" patent infringement settlements are confined almost exclusively to the pharmaceutical industry). These settlements may also permit the generic manufacturer to enter the market at a later date but *before* the

patent's expiration date. See Aggrenox, 94 F. Supp. 3d at 234. Such "pay for delay" settlements have uncertain market impacts.

> Assuming the patent is valid, and that the patentholder would ultimately prevail, such a settlement means that the patent-holder is avoiding the cost of litigation by agreeing to shorten the length of its legal monopoly and to share some of its monopoly profits with the challenger. Consumers benefit by enjoying the lower prices of generics sooner than they otherwise would under the patent. Assuming, however, that the patent is invalid, and that the challenger would ultimately prevail, then such a settlement amounts to a "pay to delay" agreement: the patent-holder's monopoly is illegitimate, and it is paying a would-be competitor to delay its entry into the market. Consumers who should enjoy competitive prices now will instead pay monopoly prices until the end of the term of the anticompetitive collusion. The availability of such settlements allows manufacturers of brand-name drugs to avoid the invalidation of potentially weak patents and keep prices high by sharing their monopoly profits with manufacturers of generics.

Id. Before Actavis, some courts reasoned that because any pay-for-delay settlement inevitably allowed generic market entry before the expiration of the brand's patent, the brand manufacturer was not gaining any exclusive time it was not already entitled to via its patent monopoly. See Actavis 570 U.S. at 146. The result was a split in circuit authority over whether such agreements could violate antitrust law.

The Supreme Court in Actavis said that they could - in certain circumstances. 570 U.S. at 141. The Court concluded that agreements containing reverse payments can harm consumers if, in exchange, the generic manufacturer agrees to abandon a meritorious

invalidity claim and enter the market later than it could have, assuming the patent were invalidated. The key issue is whether the reverse payment is "large and unjustified." The Court declined the FTC's request to adopt a presumption that such settlements are unlawful, noting that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id. at 159.

D. "No-AG" Agreements

As scrutiny over reverse payment settlement agreements increased, antitrust plaintiffs began challenging not only cash payments (at issue in Actavis), but also more complex arrangements that still provide value to generic manufacturers. The form alleged in this case is a "No-AG" agreement – a promise by a brand manufacturer "not to market an AG version of the brand drug for some period of time after the first generic enters." DPP Compl. ¶ 79; see in re Lipitor Antitrust Litig., 868 F.3d 231, 252 (3rd. Cir. 2017) (holding reverse payment may be in the form of a no-AG agreement).

No-AG agreements compensate a first-filer's delayed entry by ensuring that it will face no generic competition during its 180-

day exclusivity period. Depending on the brand's sales, the difference in generic profits can be hundreds of millions of dollars. DPP Compl. ¶ 84; see also Actavis, 570 U.S. at 153-54. These arrangements may harm consumers by extending the period of brand exclusivity and by eliminating the price competition that would result if the first-filer's generic had to compete with the brand's AG. Lost consumer savings would instead flow to the brand and generic manufacturers in the form of increased monopoly profits. See DPP Compl. ¶¶ 82-84. Numerous courts relying on the Supreme Court's reasoning in Actavis have found potential antitrust violations deriving from no-AG agreements. See, e.g., In re Loestrin 24 FE Antitrust Litig., 814 F.3d 538, 551-52 (1st Cir. 2016); King Drug Co. of Florence v. SmithKline Beecham Corp., 791 F.3d 388, 403 (3rd Cir. 2015); In re Opana, 162 F. Supp. 3d at 717; United Food & Com. Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc. (Lidoderm I), 74 F. Supp. 3d 1052, 1068-69 (N.D. Cal. 2014); In re Niaspan Antitrust Litigation, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014).

III. Factual Background

A. Merck Develops Ezetimibe and Seeks Patent Protection and FDA Approval

In the 1990s, Merck was working on a program to develop chemicals that would be useful in reducing cholesterol levels in

humans.[5] Merck researchers discovered a lead compound and several of its metabolites and metabolite-like analogues, including ezetimibe, the active ingredient in Zetia. Merck quickly sought broad patent protection for these compounds. DPP Compl. 29-31 ¶¶ 96-97.[6]

Beginning with U.S. Patent Application 102,440 in September of 1993, Merck prosecuted a series of patents over the next few years. Merck would ultimately obtain several patents on azetidinone compounds. See DPP Compl. ¶ 103, Fig. 6 (depicting application and patent history of the azetidinone patents). Plaintiffs' allegations contain an extensive history of these patents and descriptions of their respective claims. Although much of this information may become relevant later in a potential motion for summary judgment or at trial, for present purposes only a simplified account is necessary.

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[5] Although the three motions addressed in this Report are directed to three different complaints, the factual allegations describing the anticompetitive conduct are generally the same. Each motion to dismiss requires the court to accept all facts alleged in the complaint as true and draw all reasonable inferences in favor of the plaintiff. Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999).

[6] The Retailer Complaints and the EPPs' Consolidated Complaint recite substantially identical allegations to those contained in the DPPs' Complaint.

Among the patents Merck ultimately obtained was U.S. Patent No. 5,767,115 ("the '115 patent"). Plaintiffs allege that ezetimibe is within the scope of several claims in this patent. The '115 patent expired on June 16, 2015. DPP Compl. ¶¶ 123-25. As it began preparing an NDA for the compound, Merck filed a reissue application on the '115 patent. The reissue application sought to add additional claims with narrower scope directed at "one of the most preferred compounds disclosed in the specification"—specifically, ezetimibe. DPP Compl. ¶¶ 128-29.

On December 27, 2001, Merck submitted an NDA seeking approval to market ezetimibe tablets as a cholesterol-control drug under the brand name Zetia. While the NDA was pending, the PTO issued U.S. Patent No. RE37,721 ("the '721 patent"), a reissue of the '115 patent. The '721 patent included the new claims for the compound ezetimibe, a composition of ezetimibe, and a method of using ezetimibe to treat high cholesterol. The FDA approved Merck's NDA on October 25, 2002 and granted it a five-year NCE exclusivity. Merck then sought extension of the '721 patent term based on the duration of the FDA's review of the Zetia NDA. The PTO granted an extension of 497 days, which set the '721 patent's expiration date on October 25, 2016, not including pediatric exclusivity. Merck ultimately listed three patents in the Orange Book in conjunction with the Zetia NDA: (1) the '721 patent; (2) U.S. Patent No. 5,846,966, which claimed azetidinone compounds combined with

statins; and (3) U.S Patent No. 7,030,106, which claimed compounds that inhibit sterol absorption and methods for their use. DPP Compl. ¶¶ 126-45.

B. Merck Sues First-Filer Glenmark for Patent Infringement

On October 25, 2006, generic drug manufacturer Glenmark filed an ANDA seeking FDA approval to market a generic version of Zetia. Glenmark's ANDA contained a paragraph IV certification to all of the ezetimibe patents listed in the Orange Book at that time. On or about February 9, 2007, Glenmark notified Merck of its ANDA filing. Merck sued Glenmark on March 22, 2007, alleging that it was infringing the '721 patent. This triggered the automatic stay of FDA's approval of Glenmark's ANDA until the earlier of (i) the expiration of the 30-month stay, or (ii) entry of a final judgment that the '721 patent was invalid, unenforceable, or not infringed. Glenmark answered and counterclaimed, seeking declaratory judgment that the '721 patent was invalid and/or unenforceable.

Glenmark raised several arguments. It alleged that at least two compounds claimed in the '721 patent are inherent metabolites of a compound disclosed in an earlier Schering patent application. See DPP Compl. ¶¶ 155-57. Glenmark also argued that Merck's failure to disclose the inherency of these metabolites to the PTO during prosecution of the '721 patent was inequitable conduct. It alleged that Merck failed to disclose material publications that investigated these metabolites to the PTO during prosecution. It

also alleged that Merck committed inequitable conduct in seeking patent term extension for the '721 patent without disclosing that certain claims were invalid for inherent anticipation. A finding of inequitable conduct related to the prosecution of a patent invalidates the entire patent. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011). DPP Compl. ¶¶ 158-60. Glenmark also argued that the '721 patent was invalid for lack of enablement, failure to name the inventors, lack of proper reissue, and obviousness-type double patenting. DPP Compl. ¶¶ 161-65.

On April 24, 2009, the FDA tentatively approved Glenmark's Zetia ANDA. With this approval, Glenmark secured the 180-day generic exclusivity afforded to first-filers. However, Glenmark remained unable to launch its generic due to the 30-month stay triggered by Merck's infringement suit. DPP Compl. ¶¶ 166-67.

Glenmark filed two motions for partial summary judgment in the Merck/Glenmark patent litigation. Each motion focused on a discrete issue attacking the validity of the '721 patent. Specifically, Glenmark argued (1) that the '115 patent was wholly or partly invalid and therefore could not be reissued (as the '721 patent) under 35 U.S.C. § 251, and (2) that most of the claims in the '721 patent were invalid for obviousness-type double patenting. DPP Compl. ¶¶ 169-72.

On April 19, 2010, the district court granted Glenmark's motion for summary judgment on improper reissue and denied its motion on obviousness-type double patenting. The functional result of this partial ruling would have been invalidation of claims 10-13 in the '721 patent, which claimed ezetimibe expressly and had been added in reissue. Merck moved for reconsideration of the partial order on April 30, 2010. DPP Compl. ¶¶ 176-77.

C. Merck and Glenmark Settle the Infringement Suit

Two days before trial was scheduled to begin, and prior to any ruling in Merck's motion to reconsider, Merck and Glenmark reached the Settlement Agreement that is central to this case. As part of the settlement, the parties agreed to entry of a consent judgment and requested an order from the court vacating its partial summary judgment on improper reissue, thereby reinstating claims 10-13 in the '721 patent. The court referenced the Settlement Agreement in its consent judgment but did not docket the parties' written agreement in the record. DPP Compl. ¶¶ 178-82.

Plaintiffs allege that this Settlement Agreement contains a no-AG provision as quid pro quo for Glenmark's agreement to delay its generic launch until late 2016. Drafted without access to the Settlement Agreement itself, all the complaints assert certain facts which, in Plaintiffs' opinion, lead to the logical inference that Merck agreed not to launch a competing AG during Glenmark's 180-day exclusivity period in exchange for Glenmark's agreement to

delay entry. Among the allegations Plaintiffs rely on are that: (1) Merck has previously acknowledged the economic benefit of marketing AGs; (2) Merck has a history of launching AGs after its patent exclusivity expires; (3) Zetia was a blockbuster drug with billions of dollars in sales when Glenmark launched its generic in 2016; and that (4) Merck ultimately did not launch an AG during Glenmark's exclusivity period. See DPP Compl. ¶¶ 183-90.

After reviewing the Settlement Agreement itself (which was produced in discovery but remains sealed), Plaintiffs identify two provisions which, functioning together, they allege act as the contractual no-AG agreement forecast in their pleadings. The first is the definition of Generic Ezetimibe, which reads:

> The term "Generic Ezetimibe" shall mean a drug product containing ezetimibe as its sole active ingredient (a) that refers to the Approved Zetia Product as the reference-listed drug in an ANDA or pursuant to an application under 21 U.S.C. § 355(b)(2) or (b) that is sold pursuant to NDA No. 21-445 but is not sold under the trademark Zetia® or another trademark or trade name of Schering, MSP or their Affiliates.

Br. Supp. Def. Glenmark's Mot. to Dismiss DPP Compl. Ex. A "Sett. Agr." § 1.14 (filed under seal as ECF No. 159). Because any authorized generic would have to be sold pursuant to Merck's Zetia NDA, Plaintiffs allege its inclusion in the definition of Generic Ezetimibe indicates Merck intended to give up AG rights during Glenmark's exclusivity period. The second provision provides an express promise that the right to market "Generic Ezetimibe" would

be "exclusive to Glenmark" except pursuant to a third-party ANDA. It reads:

> During any period of exclusivity to which Glenmark is entitled under 21 U.S.C. § 355(j)(5)(B)(iv), and through the expiration of Schering's rights under the '721 Patent and Ezetimibe Pediatric Exclusivity, Schering's grant of the rights in Paragraphs 5.1 and 5.2 is exclusive to Glenmark and its Affiliates with respect to the commercial distribution and sale of Generic Ezetimibe, subject only to Schering's right to grant rights to or otherwise authorize Third Parties to make, have made, use, sell, offer to sell, import, or distribute Generic Ezetimibe pursuant to such Third Parties' ANDAs or applications pursuant to 21 U.S.C. § 355(b)(2).

Sett. Agr. § 5.3.

Plaintiffs claim that these provisions, and Merck's actions in not launching an AG during Glenmark's period of exclusivity, amount to a reverse payment settlement. Absent these provisions, Plaintiffs allege Glenmark would have entered the market long before 2016, possibly as early as December 6, 2011. Plaintiffs base this assertion on two alternative possibilities. First, in the absence of a reverse payment agreement, Merck and Glenmark may have agreed to settle the infringement claim with an earlier agreed entry date. The settlement would have been based on the relative merits of the parties' claims in the infringement suit and ordinary considerations over the cost of litigating the claims. DPP Compl. ¶¶ 194-200. Under this theory, Glenmark would have insisted on an earlier entry date in compromise of its claims of invalidity, but-for the compensation it received in the No-AG agreement.

As a second possibility, Plaintiffs argue that Glenmark would have prevailed in the infringement suit and secured a declaration that the '721 patent, which Merck asserted against Glenmark's generic version of Zetia, was invalid or unenforceable. Glenmark would have thereafter taken reasonable and economically rational steps to launch its generic at the earliest possible date. DPP Compl. ¶¶ 201-02.[7]

The result in either scenario would have been the earlier launch of Glenmark's generic, perhaps as early as December of 2011. Plaintiffs allege that Merck would also have launched its competing AG around the same time, and that additional generics would have entered the market after Glenmark's 180-day exclusivity expired, as early as June of 2012. DPP Compl. ¶¶ 203-04.

Plaintiffs' allegations regarding the value of a pay-for-delay, no-AG agreement to both Merck and Glenmark center on the substantial market for Zetia during the period at issue and their

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[7] In April 2011, the Court of Appeals for the Federal Circuit issued its decision in Ex parte Tanaka, 640 F.3d 1246 (Fed. Cir. 2011). In Tanaka, the court held that reissue was a proper remedy for a patentee seeking to add dependent claims "as a hedge against possible invalidity of original claims." Id. at 1249. Plaintiffs argue that while this decision functionally overturned the basis for the district court's partial summary judgment grant in the earlier Merck-Glenmark litigation, it had no impact on Glenmark's other meritorious claims of invalidity. DPP Compl. ¶¶ 227-28.

estimates of market effects from generic entry. See DPP Compl. at 58-61. Plaintiffs allege that branded Zetia sales in 2011 totaled approximately $1.3 billion. DPP Compl. ¶ 208. In a scenario where Glenmark introduced its generic in December 2011, roughly concurrent with a Merck AG, Plaintiffs allege that the generic market would have captured roughly 80% of the branded sales during the first six months (which correspond to Glenmark's 180-day first-filer exclusivity). Glenmark's generic and Merck's AG would have split those generic sales roughly in half, and the generic would have sold at half the branded price. Merck would also retain a small portion of its branded revenue, which Plaintiffs estimate at about 10% of its pre-generic volume. Combining these figures, Plaintiffs estimate Merck's total branded and generic Zetia sales at about $780 million over the five-year class period in a scenario with generic entry in December 2011. DPP Compl. ¶¶ 205-09.

Plaintiffs estimate that Merck's actual sales during the class period were between $6.5 and $9.1 billion. Subtracting the early-entry sales estimate yields a predicted value between $5.7 and $8.3 billion. In other words, Plaintiffs allege that by trading a no-AG promise for Glenmark's delayed entry, Merck earned at least $5.7 billion more in profits on Zetia sales than it otherwise would have during the class period. DPP Compl. ¶¶ 210-11.

Glenmark, Plaintiffs allege, also benefited tremendously from the agreement. Using the same assumptions as for Merck, Plaintiffs

estimate that Glenmark would have seen about $180 million in generic sales during its 180-day exclusivity period in the absence of a no-AG agreement. With the agreement, however, Glenmark captured the entire generic market during that time (which Plaintiffs allege was about 80% of the branded sales). It was also able to charge a higher price for its generic (90% of the brand price rather than 50%) owing to the lack of AG competition. Using a 2016 annual Zetia sales figure of $2.6 billion, Plaintiffs allege that Glenmark enjoyed about $936 million in generic sales during its exclusivity window. Thus, Glenmark's agreement with Merck was worth about $806 million in additional sales to Glenmark (or a lesser but still significant $225 million if the Zetia market remained flat from 2011). DPP Compl. ¶¶ 212-17.

D. Subsequent Patent Litigation between Merck and Additional Generic Manufacturers

After settling its litigation with Glenmark, Merck sought reissue of the '721 patent. In its declaration, Merck acknowledged that at least one claim in the '721 patent was potentially invalid for inherent anticipation by Merck's earlier disclosures. See DPP Compl. ¶¶ 218-20. The '721 patent would eventually reissue as U.S. Patent No. RE42,461 ("the '461 patent"). As reissued, it included claims 8 through 13 and parts of claims 3 and 7 of the '721 patent. DPP Compl. ¶¶ 229-30.

In mid-2010, generic manufacturers Mylan Pharmaceuticals, Inc. ("Mylan") and Teva Pharmaceuticals ("Teva") each filed paragraph IV ANDAs seeking approval to market generic Zetia. Merck sued both manufacturers after receiving notice of their filings. DPP Compl. ¶¶ 221-26. Teva would later settle its claims with Merck by confidential agreement on July 7, 2011. The court entered a consent judgment that prohibited Teva from launching its generic version of Zetia before April 25, 2017. Teva also admitted that its generic infringed the '461 patent. DPP Compl. ¶ 231.

The Mylan litigation continued without settlement. After Merck substituted the reissued '461 patent for the '721 patent, Mylan filed an answer and counterclaims. Mylan argued that Merck's patent was invalid for inherent anticipation and unenforceable for failure to disclose prior art and for failure to disclose an ezetimibe inventor. The court denied Merck's motion for summary judgment on the inequitable conduct issue but granted Merck's motion on infringement, concluding that Mylan's ANDA infringed claims 3, 10, 11, and 12. DPP Compl. ¶¶ 232-35.

On November 18, 2011, Mylan withdrew its defense "based on the non-disclosure of information demonstrating a relationship between compounds claimed in predecessor patents and metabolites of a prior art compound." DPP Compl. ¶ 237. Plaintiffs allege that Mylan's decision was not a reflection of the relative substantive merits of its various arguments but simply a recognition of Mylan's

present litigation position. Because it was not a first-filer, Mylan's potential gains if it succeeded in its litigation were smaller than Glenmark's had been. Mylan would likely be faced with immediate and substantial generic competition on entering the market and would have to wait out Glenmark's 180-day exclusivity in any case. As Plaintiffs characterize it, "Mylan's litigation strategy reflected the choice of not necessarily the best substantive defense, but the cheapest and fastest within the practical constraints." DPP Compl. ¶¶ 238-39.

The Mylan case proceeded to a bench trial. The sole issue at trial was whether the '461 patent was unenforceable for inequitable conduct by Merck in allegedly misrepresenting the inventorship. The court ruled that Mylan had failed to prove inequitable conduct on this issue and therefore upheld the '461 patent against that challenge. The Federal Circuit later affirmed the district court. DPP Compl. ¶¶ 240-41, 241 n.62.

In August 2012, Sandoz filed its own generic Zetia ANDA. Merck sued Sandoz for infringement of the '461 patent. Sandoz counterclaimed seeking a declaratory judgment of invalidity and unenforceability. Among other arguments, it alleged the '461 patent was unenforceable for inequitable conduct based on Merck's failure to disclose certain publications concerning metabolites of a prior art compound. On September 5, 2013, before the pleadings stage of the suit was complete, Merck and Sandoz settled. Sandoz

admitted the '461 patent was valid and infringed and agreed not to launch its generic before April 25, 2017. DPP Compl. ¶¶ 243-47.

IV. Standard of Review

"A pleading that states a claim for relief must contain ... a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A pleading fails to meet this standard and is subject to dismissal under Rule 12(b)(6) when it does not "contain sufficient factual matter, accepted as true, to 'state a claim that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the plaintiff pleads factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Factual allegations must be enough to raise a right to relief above the speculative level" and beyond the level that is merely conceivable. Twombly, 550 U.S. at 555. Legal conclusions and "[t]hreadbare recitals of the elements of a cause of action" do not state a claim. Iqbal, 556 U.S. at 678.

The United States Supreme Court has described the motion to dismiss analysis in two parts. First, the court must accept the allegations of fact as true. Id. However, a court is not required "to accept as true a legal conclusion couched as a factual allegation," Papasan v. Allain, 478 U.S. 265, 286 (1986), or a

legal conclusion unsupported by factual allegations, Iqbal, 556 U.S. at 678-79. After reviewing the allegations, the court must then consider whether they are sufficient to state a plausible claim for relief. This is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. A Rule 12(b)(6) motion, then, should be granted if, "after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999).

"In antitrust cases in particular, the Supreme Court has stated that 'dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly.'" Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp., 910 F.2d 139, 144 (4th Cir. 1990) (quoting Hospital Bldg. Co. v Trs. of Rex Hosp., 425 U.S. 738, 747 (1976)).

V. Analysis

Defendants raise two primary arguments in favor of outright dismissal of all antitrust claims. First, they argue that the written Settlement Agreement resolving the Merck/Glenmark litigation undermines Plaintiff's allegations that it included a "large and unjustified" reverse payment as required by Actavis.

Secondly, Defendants contend that Merck's successful defense of the '721 patent in its later litigation with Mylan renders Plaintiffs' claims of anticompetitive effect implausible. Mylan's loss, according to Defendants, undermines Plaintiffs' allegations that Glenmark would have succeeded in its Paragraph IV challenge, thus forcing earlier generic entry. Additionally, Defendants' argue the § 2 Sherman Act claims falter on Plaintiffs' failure to plausibly allege a specific intent to monopolize.

The Plaintiffs contend that the written Settlement Agreement supports rather than undermines their other allegations of a reverse payment settlement between the two companies. They argue that the language of the Settlement Agreement is fully consonant with those allegations and supports the claim that Merck's promise not to introduce an authorized generic constituted a large and unjustified reverse payment. Plaintiffs also contend that Merck's defeat of Mylan's later challenge to the validity of the '721 patent does not preclude their claims of anticompetitive effect because they were not parties to the Mylan litigation. They also note that Glenmark had obtained a favorable ruling on summary judgment and alleged several other bases to invalidate the '721 patent-arguments not pressed by Mylan. These allegations are also sufficient, Plaintiffs claim, to plausibly support their claims of conspiracy to monopolize under § 2.

A. Plaintiffs have Plausibly Alleged a Claim under § 1 of the Sherman Act Arising from a Reverse Payment Settlement between Merck and Glenmark.

Section 1 of the Sherman Act broadly prohibits contracts or "combination[s] in restraint of trade," 15 U.S.C. § 1. Not every agreement resolving brand-generic patent litigation produces the anti-competitive effects the Sherman Act sought to address. Only settlement agreements that have "genuine adverse effects on competition" plausibly give rise to antitrust remedies. Actavis, 570 U.S. at 153 (quoting FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 460-61 (1986)).

Patent holders already enjoy the right to exclude competition for the duration of their patents. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 ("[A] patent ... is an exception to the general rule against monopolies." (quoting Precision Instrument Mfg. Co. v. Auto Maint. Mach. Co., 324 U.S. 806, 816 (1945)). As a result, settlements of Paragraph IV litigation, which frequently allow the generic manufacturer to enter earlier than the patent's expiration, do not always produce antitrust harm. If they do not include a reverse payment from the patentee as compensation for the generic's agreement to delay generic entry, they are more likely to reflect the compromise of disputed issues than an allocation of monopoly profits. Actavis, 570 U.S. at 158. But where the settlement includes a payment from the patent holder to an alleged infringer, the question presented

is, what are the reasons for the payment? If the payment represents no more than "a rough approximation of the litigation expenses saved through the settlement … [or] compensation for other services that the generic has promised to perform," there is less concern the settlement is intended to divide and extend the monopoly. Id. at 156. But very large payments may not be justified by such traditional settlement considerations. "An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." Id. at 157. If so, then its objective may be "to maintain supracompetitive prices to be shared among the patentee and the challenger." Id. Such "large and unjustified" reverse payments raise antitrust concerns and subject the agreement to scrutiny for antitrust harms. Id.

Since Actavis was decided, the Fourth Circuit has not had occasion to address the precise contours of pleading reverse payment antitrust claims. But those appellate courts which have examined them, require no heightened level of pleading detail. See Loestrin 24, 814 F.3d at 542 (requiring "facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis"); King Drug Co., 791 F.3d at 409-10. In the case of a reverse payment based on allegations of a no-AG agreement, the Third Circuit held it sufficient for the Plaintiff to allege the manufacturer "had an

incentive to launch its own authorized generic" and did not do so, and that the alleged infringer would earn "many millions of dollars in additional revenue," from the no-AG agreement. King Drug Co., 791 F.3d at 410. These courts recognize that "the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts." Loestrin 24, 814 F.3d at 552. But antitrust litigation "often requires an 'elaborate inquiry into the reasonableness of a challenged business practice.'" Id. (quoting Arizona v. Maricopa Cty. Med. Soc'y., 457 U.S. 332, 343 (1982)). And the absence of detailed support for the value of a no-AG promise should not bar the claim at the pleading stage. Id.

In this case, detailed factual allegations in the Complaints support the Plaintiffs' claim that the Merck/Glenmark settlement included a large and unjustified reverse payment. As recited earlier, the Complaints allege in detail the regulatory framework encouraging generic competition in the pharmaceutical market and the powerful price effects it produces. DPP Compl. ¶¶ 28-64. They allege that Merck had "a well-established history" of launching AG competitors after losing its exclusivity on other brand name drugs. DPP Compl. at ¶ 185 (identifying 12 Merck branded drugs for which the company produced an AG). Zetia was a highly profitable drug and introducing an AG to compete with Glenmark's generic would have been in Merck's financial interest. DPP Compl. ¶¶ 63-64, 186, 211. Plaintiffs also allege that Merck expressly agreed not

to do so in the case of Zetia. DPP Compl. ¶¶ 62, 183. On announcing its entry to the generic market, Plaintiffs allege Glenmark issued a press release stating that it would be selling the "first and only generic version of Zetia in the United States." DPP Compl. ¶ 187. Most importantly, Merck did not produce an authorized generic version of Zetia, leaving the generic market entirely to Glenmark during its 180-day period of exclusivity. DPP Compl. ¶¶ 57, 191, 216. Finally, Plaintiffs estimate the value to Glenmark of Merck's agreement not to introduce an AG at between $225 and $806 million. DPP Compl. ¶¶ 216-17. All of these claims must be taken as true on a motion to dismiss.

Defendants argue that all these factual claims are rendered implausible by the language of the written Settlement Agreement itself, which they claim preserved Merck's ability to launch an AG and to compete with Glenmark through "conventional commercial conduct." Sett. Agr. § 7.2(c). After reviewing the language of the Settlement Agreement in detail, this Report concludes that it does not unambiguously contradict any of Plaintiffs' claims. In fact, construing the Agreement in the light most favorable to Plaintiffs, it actually supports the claim that Merck agreed to limit competition from an authorized generic version of ezetimibe.

1. The written Settlement Agreement does not unambiguously contradict Plaintiffs' allegations of a no-AG agreement.

The Merck/Glenmark Settlement Agreement expressly provides Glenmark with the exclusive rights to distribute "Generic Ezetimibe" during its 180-day period of exclusivity. Sett. Agr. § 5.3. The definition of "Generic Ezetimibe" includes not only generics offered by generic competitors under separate ANDA filings, but also any drug sold pursuant to the Zetia NDA, unless the drugs were sold "under the trademark Zetia® or another trademark or trade name of Schering, MSP or their Affiliates." Sett. Agr. § 1.14. According to Defendants, this reservation language in the definition of Generic Ezetimibe would have allowed Merck to introduce an AG in competition with Glenmark and thus all of Plaintiffs' allegations of a no-AG agreement are no longer entitled to the presumption of truth.

Ordinarily, documents outside the complaint not expressly incorporated may not be considered by the court on a motion to dismiss without converting it to a motion for summary judgment. Witthohn v. Fed. Ins. Co., 164 F. App'x 395, 396 (4th Cir. 2006). However, the court may examine "documents sufficiently referred to in the complaint so long as the authenticity of these documents is not disputed." Id. at 396 (citing Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co., 267 F.3d 30, 33 (1st Cir. 2001)); see also Phillips v. LCI Int'l, Inc., 190 F.3d 609, 618 (4th Cir. 1999)

(permitting consideration of extraneous material if such materials are "integral to and explicitly relied on in the complaint"). In this case, no party has disputed the authenticity of the Settlement Agreement. Because the Agreement memorializes a settlement which is integral to the Plaintiffs' Complaint, the court may consider it without converting the motion into one for summary judgment. But its language is only relevant if it unambiguously contradicts the factual claims in the Complaint. It does not.

Considering documents outside the pleadings does not alter the standard of review on a motion to dismiss requiring that facts and reasonable inferences from those facts must be examined in the light most favorable to the Plaintiffs. And even without any special deference, it is clear that the language of the Settlement Agreement would not permit Merck to sell an AG under the generic name, ezetimibe. A plain language interpretation of the clause suggests the reservation's most likely purpose was to preserve competition only from branded drugs. As a result, the contract language dos not render Plaintiffs' claims of a reverse payment no-AG agreement implausible.

First, in light of the other allegations in the Complaint, the Agreement's clear reservation of the ability to sell branded Zetia does not undermine the Plaintiffs' antitrust claims. Plaintiffs have not alleged that Merck could not compete by continuing to sell branded Zetia, by lowering its price, or

generally trying to preserve its market share after generic entry. But the economics of generic competition, which are alleged in detail in the DPP's Consolidated Complaint, plausibly support Plaintiffs' claims that competition from the branded drug Zetia would not diminish the alleged value of the no-AG agreement to Glenmark. See DPP Compl. ¶¶ 54-55, 212-15.

Slightly more difficult is the question of whether a drug sold pursuant to Merck's NDA under "another trademark or trade name of Schering, MSP, or their Affiliates" might still qualify as an AG. If so, it might have competed with Glenmark's own generic sufficient to undermine the plausibility of the facts supporting Plaintiffs' claimed value of the no-AG agreement to Glenmark, and hence its claims of a "large and unjustified" reverse payment. On this point the parties strongly dispute what the written document would permit. Defendants argue that reservation of the ability to market a drug pursuant to Merck's NDA and under a "trade name" suggests that Merck retained the ability to market an authorized generic product so long as the company's name (i.e. Merck) appeared on the label. In support, Defendants cited the provisions of 21 U.S.C. § 355(t)(3). This code section requires the FDA to maintain a database listing of all "authorized generic drugs." The statute defines an "authorized generic" for purposes of inclusion in the database as a listed drug which is sold "under a different labeling, packaging, ... product code, labeler code, trade name,

or trade mark than the listed drug." § 355(t)(3)(B). Because the statute uses terms similar to the Settlement Agreement - namely, trade name and trademark - Defendants argue that the Settlement Agreement must be read to permit Merck to release an AG competitor.

This argument reads too much into the language of the statutory listing requirements and ignores the Settlement Agreement's language mandating any drug excluded from the definition of Generic Ezetimibe must be sold "under" a Merck trademark or trade name. The reservation does not mirror the language of § 355(t)(3) exactly. As a result, if it is relevant to interpreting the Agreement, its language suggests that certain AGs - including those sold using a "different labeling, packaging product code [or] labeler code" - would be included in the Agreement's definition of Generic Ezetimibe and thus exclusive to Glenmark during its 180-day window.

The parties' briefing did not fully address the relevance of the FDA database required by subsection 355(t). But the statute reinforces the regulatory process which provides that all AGs are approved under the brand's NDA (as opposed to a competitor's separate ANDA). Because any authorized generic would have to be approved pursuant to Merck's NDA for Zetia (NDA #21-445), the Settlement Agreement's reference to the NDA in the definition of Generic Ezetimibe most likely indicates that Merck intended to

limit its ability to launch an AG. Otherwise, why would there be any reference to the NDA in this defined term?

The Defendants urge the court to construe the Agreement's use of the term "trade name" in section 1.14 to mean any name the company uses in trade – including its company name, Merck. But an earlier provision of the same statutory section suggests that the term "trade name" means something other than the name of the manufacturer. See 21 U.S.C. § 355(t)(1)(A)(i) specifying that entries in the database are to include a "drug trade name, brand company manufacturer, and the date the authorized generic entered the market").

More importantly, generic drug names like ezetimibe are expressly not trade names. Generic drug names do not belong to the drug manufacturers, but are assigned to the drug by the United States Adopted Names Council, an official body of the American Medical Association.[8] The AMA's description of the USAN Council notes that it is responsible for "selecting simple, informative

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[8] See Daphne E. Smith Marsh, Overview of Generic Drugs and Drug Naming, Merck Manual Consumer Version (Aug. 2017), www.merckmanuals.com/home/drugs/brand-name-and-generic-drugs/overview-of-generic-drug-and-drug-naming.

and unique non-proprietary (generic) drug names."[9] Thus, the name ezetimibe - under which generic forms of the drug are sold - is by definition nonproprietary and therefore not a trade name. And pharmaceuticals are not sold "under" a manufacturer's name, but under either a trademarked specialty name for branded drugs (e.g. Zetia, Lipitor, or Celebrex) or under the generic name assigned by the USAN Council (e.g. ezetimibe, atorvastatin, celecoxib). In either case the manufacturer's name (Merck, in the case of Zetia) would appear on the label.

So even if the court construed the Settlement Agreement's use of the term trade name to allow Merck to market something with a different trade name that might be recognized as an AG under the terms of § 3351(t)(3), it would not fundamentally change Plaintiffs' theory. The Agreement's plain language would still prevent Merck from selling an AG under the nonproprietary name ezetimibe. In fact, Plaintiffs concede that the reservation in the definition of Generic Ezetimibe would permit the sale of branded Zetia or another branded drug (should Merck choose to launch one) using the same active ingredient. Absent additional evidence regarding the parties' intention in crafting the

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[9] United States Adopted Names Council Home Page, www.ama-assn.org/about/united-states-adopted-names/usan-council (last visited January 29, 2019) (emphasis added).

definition of Generic Ezetimibe in the Settlement Agreement, this is the most that can be said of Merck's ability to compete in the generic market during the 180-day period of Glenmark's exclusivity. And this reservation - the ability to make another branded competitor - is insufficient to contradict and render implausible all of Plaintiffs' express allegations of a large reverse payment resulting from the no-AG agreement.

The Complaint describes dynamics of the market for generic drugs which produce rapid price decreases following generic entry. DPP Compl. ¶¶ 50-53. It asserts that "every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions." DPP Compl. ¶ 51. It describes generics as "essentially commodities" with price as the primary basis for competition. DPP Compl. ¶ 50. It also describes the effects of brand manufacturers selling an AG. DPP Compl. ¶¶ 59-64. Like other generics, AGs primarily compete on price. These allegations, accepted in the light most favorable to Plaintiffs, are sufficient to establish a significant value in Merck's promise not to launch an AG under the generic name "ezetimibe." The other allegations in the Complaint, and the language of the Settlement Agreement itself, are sufficient to plausibly allege that they made such a promise. This is particularly so in light of other corroborating evidence of the Agreement, including Glenmark's claims to

exclusivity on release of its generic ezetimibe and Merck's failure to release any authorized generic in competition with Glenmark's generic product throughout the 180-day period of exclusivity.

At this stage of the proceedings, it is not necessary for the court to finally resolve the meaning of Generic Ezetimibe which was exclusively reserved to Glenmark under the Settlement Agreement. Plaintiffs have expressly pled the existence of a no-AG agreement, as well as other corroborating facts. Although the court could disregard facts which were contradicted by unambiguous language of the written Settlement Agreement, reservation of the right to sell branded Zetia, or another trademarked or trade-named drug with the same active ingredient would not so diminish the value of the no-AG agreement Plaintiffs have alleged as to render their claims deficient. Because the Settlement Agreement appears to reserve only these options to Merck, the language of that Agreement does not undermine the allegations of a large and unjustified reverse payment.

2. Merck's vindication of the patent in the Mylan litigation does not diminish the plausibility of Plaintiffs' allegations of anticompetitive effect.

Defendants also challenge the § 1 claim on the grounds that Plaintiffs have failed to plausibly allege anticompetitive effects. This argument is based on Merck's later defeat of a challenge to the validity of a reissued version of the '721 patent in litigation it filed against Mylan labs, another generic

competitor. Because Merck upheld the patent in its later litigation with Mylan, Defendants argue that Plaintiffs' allegation that Glenmark would have prevailed in the Merck/Glenmark litigation and entered the market with a generic competitor earlier is rendered implausible. According to Defendants, absent Glenmark's ability to invalidate the '721 patent and begin generic competition earlier, its decision to delay entry did not produce any anticompetitive effect. Instead, its delay simply respected Merck's valid patent exclusivity through the remainder of the term.

As with Defendants' contractual arguments, the Plaintiffs counter by noting the express allegations in the Complaint which suggest that the Merck/Glenmark settlement produced anticompetitive effects. They allege that but for the no-AG promise, the strength of Glenmark's patent challenge would have produced one of two outcomes. The two companies would have settled with an earlier generic entry date, or Glenmark would have prevailed in the litigation, invalidated the '721 patent, and launched its generic thereafter. DPP Compl. ¶¶ 199-203. Plaintiffs allege either of these alternative outcomes would have accelerated generic entry and reduced prices. DPP Compl. ¶¶ 78-88, 203-204. Both outcomes depend on the plausibility of Plaintiffs' allegations that Glenmark's patent claims against Merck had substantial merit. If these allegations are plausible,

the § 1 claim alleges anticompetitive effect because Glenmark's delay is not entirely out of respect for a valid patent, but rather the result of the Defendants' agreement to allocate unlawful monopoly profits obtained by paying Glenmark to delay generic entry in the form of the no-AG agreement.

As alleged in the Complaint, Glenmark's validity and enforceability claims against the '721 patent relied in part on the theory that certain compounds claimed in the '721 patent were inherent metabolites of a compound disclosed in an earlier Schering patent application. DPP Compl. ¶¶ 155-57. Glenmark claimed Merck failed to disclose these metabolites to the PTO during the reissue proceedings. It also alleged other failures to cite prior art, and that the combination of these failures to disclose amounted to inequitable conduct, which would invalidate the entire patent. DPP Compl. ¶¶ 158-60. None of these claims were litigated to final resolution in the Mylan case.

Plaintiffs also allege that Glenmark argued Merck may have failed to name all inventors of ezetimibe and that the '721 patent was invalid for obviousness-type double patenting over the claims of the earlier expiring '365 patent. DPP Compl. ¶¶ 163-65. Finally, Glenmark argued that certain claims in the '721 patent were invalid because Merck failed to identify in the predecessor patent the type of error that can be corrected on reissue. DPP Compl. ¶ 164.

Glenmark moved for summary judgment on two of its claims, and shortly before trial the district court granted summary judgment on one and denied the other. Specifically, the court granted Glenmark summary judgment on its claim of improper reissue, finding that Merck had failed to identify a type of error subject to correction on reissue. The court denied Glenmark's other argument, concluding that disputes of material fact precluded summary judgment on its obviousness-type double patenting claims. DPP Compl. ¶ 171. Merck did not move for summary judgment on any of Glenmark's claims, and the remaining arguments, including the claims of inherent anticipation and inequitable conduct, were reserved for trial at the time the parties settled. DPP Compl. ¶¶ 178-80.

Following its settlement with Glenmark, Merck sought reissue of the '721 patent to correct errors in certain claims. The reissue petition acknowledged that at least one claim in the '721 patent was potentially invalid for inherent anticipation as a result of the metabolite issue. DPP Compl. ¶¶ 218-20. Merck also faced new paragraph IV filings from Teva, Sandoz, and Mylan, and brought infringement actions against each. Both the Teva and Sandoz matters settled, but Mylan's proceeded to a bench trial before the same district judge who had presided over the Merck/Glenmark litigation. DPP Compl. ¶¶ 240-41. As in the Glenmark case, Mylan argued that Merck's patent was invalid for

inherent anticipation and unenforceable as a result of its failure to disclose prior art. Mylan also alleged inequitable conduct in the failure to disclose an ezetimibe inventor. Merck moved for summary judgment on the inequitable conduct claims, which the district court denied. Later, Mylan withdrew its defenses based on failure to disclose compounds claimed in predecessor patents and inherent metabolites of prior art. DPP Compl. ¶ 237. The company proceeded to trial solely on the basis of its claim that Merck committed inequitable conduct in failing to disclose a named ezetimibe inventor. The district court resolved this issue in favor of Merck and upheld the patent against this remaining challenge. DPP Compl. ¶¶ 240-41.

As the foregoing summary demonstrates, Merck's defense of the patent in litigation initiated after the Merck/Glenmark settlement does not entirely negate Plaintiffs' claims of anticompetitive effects resulting from that settlement. Although the Mylan litigation may eventually bear on Plaintiffs' claims of anticompetitive effect, important differences between the Mylan and Glenmark challenges undercut the Defendants' argument that Plaintiffs' claims of anticompetitive effect lack plausibility.

In In re Lipitor Antitrust Litigation, the Third Circuit addressed and rejected a similar claim. 868 F.3d 231. There, the district court had dismissed antitrust claims alleging Walker Process fraud largely because a different district court had

rejected similar allegations and foreign courts had upheld the patent against the related fraud claims in previous litigation. Id. at 267. The Third Circuit reversed the district court's dismissal, finding that the lower court's reliance on cases to which plaintiffs had not been party "amounted to the application of collateral estoppel and was therefore improper." Id.

While not precisely analogous, the Third Circuit's opinion is instructive. There, as here, the issue was not whether the plaintiff was literally bound by a prior ruling, but whether a prior ruling contrary to the facts alleged in the case before the court could render those allegations implausible. After noting that numerous factors prevented the direct application of collateral estoppel, the court also held that the prior decisions had no bearing on the plausibility of allegations made by the plaintiff before it. Id. at 269. Resolution of similar fraud allegations in litigation not involving those plaintiffs "should not dictate the plausibility of ... plaintiff's allegations when they were not parties to that litigation." Id.

Likewise here, the outcome of the Mylan litigation does not dictate the plausibility of Plaintiffs' allegations of anticompetitive effect. In addition to the fundamental issue that none of these Plaintiffs were parties to the prior litigation, the Mylan and Glenmark challenges were both procedurally and factually different. Procedurally, it is obvious that at the time of the

Merck/Glenmark settlement, the litigating parties were in a significantly different posture than Mylan and Merck. Glenmark had already secured first filer status and would profit immensely from its 180-day period of exclusivity. Mylan, though it might force generic entry sooner, would still not enjoy any period of exclusive distribution and its concomitant period of higher margins on generic sales. DPP Compl. ¶ 55 (alleging 80% of first-filing generic's lifetime profit is earned during period of exclusivity).

Glenmark had also already persuaded the trial judge that certain claims in the '721 patent were invalid as a result of improper reissue. Several other of Glenmark's arguments were set for trial, suggesting Merck did not believe any were subject to dismissal on a motion for summary judgment. Although the Federal Circuit later reversed the precedent underlying Glenmark's summary judgment win, the facts alleged in this court establish that at the time of the settlement, Glenmark's case against the Merck patent could plausibly be described as very strong.

The question to be examined in this litigation is not whether later-developed facts undermined the strength of Glenmark's claims. Rather, it is whether the parties' actions at the time of the settlement were motivated exclusively by traditional settlement considerations or, as Plaintiffs allege, the allocation of monopoly profits to unlawfully extend Merck's patent

exclusivity. In this regard, the existence of a large reverse payment in the form of a no-AG agreement disproportionate in value to anticipated litigation costs, and independent from services to be rendered or other justifications, makes the possibility of such anticompetitive effects far more likely. Lipitor, 868 F.3d at 256 (citing Actavis, 570 U.S. at 59).

In short, the fact that Merck successfully defeated a single challenge by a later-in-time ANDA filer does not totally undermine Plaintiffs' claims of anticompetitive effect. The no-AG settlement Plaintiffs allege arose almost two years before Merck's win in the Mylan case. DPP Compl. ¶ 241. Despite not having discovery, Plaintiffs have also credibly alleged that Mylan's decision to abandon certain claims of inequitable conduct was motivated by practical trial strategy and its dim prospects for obtaining first filer status as to any of Merck's branded cholesterol drugs. DPP Compl. ¶¶ 237-39. The no-AG Agreement alleged in the Complaint plausibly asserts a large and unjustified payment to a first filer. Such payments "remove[] from consideration the most motivated challenge to a suspect patent." Actavis, 750 U.S. at 155 (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1586 (2006)). The Supreme Court recognized the "special advantage that the 180-day exclusivity period gives to first filers," and the resulting incentive to

patent holders in this context to overcome the ordinary incentives to resist paying off such challengers. Id. at 156. Plaintiffs have plausibly alleged that Merck and Glenmark reached such an agreement and the court should DENY Defendants' motion to dismiss the § 1 Sherman Act claims.

B. Plaintiffs' Allegations of a No-AG Reverse Payment Settlement Agreement Plausibly Allege a Conspiracy to Monopolize the Market for Ezetimibe under § 2 of the Sherman Act.

Defendants also moved to dismiss Plaintiffs' claims under § 2 of the Sherman Act, which allege a conspiracy to monopolize trade. 15 U.S.C. § 2. They argue that Plaintiffs' § 2 claims fail for the same reasons already analyzed in regard to their § 1 claims. They also claim that Plaintiffs have failed to plausibly allege facts sufficient to support the specific intent required of a conspiracy to monopolize.

To state a claim under § 2, Plaintiffs must allege a "concerted action, a specific intent to achieve an unlawful monopoly, and commission of an overt act in furtherance of the conspiracy." Advanced Health-Care Servs., 910 F.2d at 150. While a conspiracy does require proof of specific intent, the overt acts of each alleged conspirator do not themselves need to be predatory. Id. Specific intent refers to an intent to conspire, "a meeting of minds in an unlawful arrangement." Am. Tobacco Co. v. United States, 328 U.S. 781, 810 (1946).

The cases Defendants cite in support of this brief argument do not support dismissal. In fact, Advanced Health-Care Services, which the Defendants rely on for the elements of the claim, reversed a district court's dismissal of § 2 claims where the Plaintiff had alleged a conspiracy to monopolize a regional market for durable medical equipment (DME). 910 F.2d at 150. That case involved allegations of exclusionary contracts between hospitals and another DME supplier. The Fourth Circuit wrote that the agreements themselves and their implementation were sufficient to state a colorable claim for conspiracy to monopolize the DME markets around the hospitals. See id. at 147-49. While not precisely analogous, the Plaintiffs here have also alleged that the Merck/Glenmark Settlement Agreement involved a contract which sought to extend Merck's monopoly for the sale of ezetimibe and exclude competitors by preventing competition from an authorized generic. The Complaint details Merck's monopoly power, derived from direct evidence of its ability to control the price of ezetimibe and exclude competitors. DPP Compl. ¶ 280. It alternatively pleads a relevant market, both in terms of product and geography. DPP Compl. ¶¶ 281-82; see E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 450 (4th Cir. 2011). Plaintiffs also allege that the Settlement Agreement provided Glenmark with exclusive rights to sell Generic Ezetimibe for the lucrative 180-day first-filer window, and that Glenmark agreed to

settle its patent claims in order to receive this exclusive arrangement. DPP Compl. ¶¶ 212-17. "[A] monopolist's use of exclusive contracts, in certain circumstances, may give rise to a § 2 violation even though the contracts foreclose less than [a] 40% to 50% share." United States v. Microsoft Corp., 253 F.3d 34, 70 (D.C. Cir. 2001). Allegations of a dominant market share, combined with exclusionary contracts, are generally sufficient to state a § 2 claim. See E.I. du Pont de Nemours, 637 F.3d at 452; Advanced Health-Care Servs., 910 F.2d at 147.

Defendants do not contest Plaintiffs' pleading with respect to § 2's requirements of overt acts or antitrust injury. Because the facts alleged in the Complaint are also sufficient to plausibly support the specific intent necessary to state a conspiracy claim, the court should DENY the Defendants' motion to dismiss the § 2 claims.

C. The Retailer Plaintiffs Have Failed to Plausibly Allege a Per Se Violation of § 1 of the Sherman Act, or Any Claim for Injunctive Relief.

The Retailer Plaintiffs' three Complaints also allege a per se violation of § 1, arguing that the Merck/Glenmark Settlement Agreement is per se illegal under the Sherman Act. Retailers claim the Agreement includes a horizontal market allocation, output restriction, and price fixing agreement, all of which they argue presumptively violate longstanding antirust precedent. See e.g., Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643 (1980) (holding

competitors' price fixing agreement was illegal per se); United States v. Topco Assocs., Inc., 405 U.S. 596 (1972) (agreement among competitors to allocate market geographically is illegal per se).

Per se analysis under the Sherman Act apples to such agreements because repeated review of similar conduct produced the consistent conclusion that it was "plainly anticompetitive," lacking any "redeeming virtue." Broadcast Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 9-10 (1979). The per se rule "permits courts to make 'categorical judgments' that certain practices, including price fixing, horizontal output restrictions, and market-allocation agreements, are illegal per se." Continental Airlines, Inc. v. United Airlines, Inc., 277 F.3d 499, 509 (4th Cir. 2002) (quoting Northwest Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co., 472 U.S. 284, 289 (1985)). But it is only appropriate after courts have had considerable experience with the type of restraint at issue, and only if courts can predict with confidence that such agreements "would be invalidated in all or almost all instances under the rule of reason." Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 886-87 (2007).

This authority demonstrates that the Retailers have failed to plausibly allege a per se violation of § 1. Most fundamentally, this is because Retailers' allegations of market allocation, output restriction, and price fixing ignore Merck's existing

patent rights. Absent a loss in the Merck/Glenmark patent litigation, Merck already enjoyed the right to exclude Glenmark as a competitor beyond the entry date fixed by the Settlement Agreement. The same patent monopoly allowed Merck to set prices for its branded Zetia throughout the term of the patent and to license other manufacturers to produce the drug, all without running afoul of the per se rules. See Broadcast Music, 441 U.S. at 24-25 (analyzing license agreement under the rule of reason).

While Retailers have alleged that Merck's patent was subject to Glenmark's invalidity challenge and thus insufficient to support the reverse payment alleged, those facts are sharply in dispute. The problem with Retailers' per se claim is that it would eliminate Defendants' right to contest the issue. A claim of a per se price fixing agreement, for example, depends upon the existence of a naked agreement to fix prices. See Ratino v. Med. Serv. of Dist. of Columbia, 718 F.2d 1260, 1269-70 (4th Cir. 1983). Retailers have not alleged such an agreement because the agreement they do allege also settled contested patent litigation that would have affected Defendants' ability to set prices.

Actavis itself recognized that certain patent Settlement Agreements could have procompetitive effects, including (as in this case) permitting generic competition before the scheduled patent term expires. See Actavis, 570 U.S. at 154. In addition, settling parties may lawfully provide for payments premised on

"traditional settlement considerations such as avoided litigation costs or fair value for services." Id. at 156. In making these observations, the Supreme Court rejected the more cursory "quick look" review of reverse payment settlement agreements urged by the FTC. Id. at 159. And in so doing, the Court implicitly held that per se treatment of reverse payment settlements was inappropriate.

Much of the Retailers' briefing on this point is spent analogizing the market effects of the Settlement Agreement to forms of anticompetitive conduct which make up the "principal per se rules." Retailers Br. at 11. They observe that the Defendants agreed in the Settlement Agreement to "allocate" the market for ezetimibe exclusively to Merck until the generic entry date fixed by the Agreement. Thereafter, they argue that the market for Generic Ezetimibe would be reserved to Glenmark for its 180-day first-filer window. But for a per se violation based on market allocation to exist, such an allocation would have to be the sole – or at least a primary – purpose of the Agreement. Such a claim, which would be essential to the already strained market-allocation analogy, is rendered implausible by Merck's existing patent. In short, before the paragraph IV filing Merck already retained the right to legally "allocate" the ezetimibe market to preclude competition from Glenmark. Likewise, Glenmark's status as a first filer earned it a 180-day period of exclusivity precluding competition from other generic makers. Retailers' claimed per se

bar fails to account for the complexity presented by these facts. Indeed, application of a per se rule would appear to preclude a mechanism for even examining the Defendants' proffered justifications for settlement. For this reason, courts analyzing reverse payment agreements have consistently applied the rule of reason analysis. In re Lipitor Antitrust Litig., 855 F.3d 126, 136, 140 (3rd Cir. 2017); In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 41-42 (1st Cir. 2016).

The Retailers' claims of a horizontal output restriction and horizontal price fixing have the same fatal defect. Each relies solely on a characterization of the Agreement's effects while ignoring entirely the admittedly lawful basis Defendants assert for those same effects.

There may come a time when reverse payment settlements are sufficiently uniform that "courts can predict with confidence that [they] would be invalidated in all or almost all instances under the rule of reason. Leegin Creative, 551 U.S. at 886-87. But that time does not appear close at hand. FTC v. Abbvie, Inc., 107 F. Supp. 3d 428, 436-37 (E.D. Pa. 2015) (finding that alleged reverse payment agreement was "procompetitive" and granting defendants' motion to dismiss), appeal docketed No. 18-2621 (3d Cir. Jul. 23, 2018); In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734 (E.D. Pa. 2015) (granting summary judgment for defendants in reverse payments case after applying rule of reason

analysis); aff'd, 868 F.3d 132 (3rd Cir. 2017). Accordingly, this Report recommends the court GRANT Defendants' motion to dismiss Count 1 of the Retailer's Complaint which asserts per se claims under § 1 with prejudice.[10]

Defendants also moved to dismiss Retailers' request for injunctive relief. Walgreens Compl. ¶¶ 218-19; Rite Aid Compl. ¶¶ 217-18; CVS Compl. ¶¶ 217-18. They argue that Retailers' complaints do not allege any ongoing conduct to enjoin as the market for ezetimibe is now fully competitive with multiple generic competitors. The Retailers - the only group of plaintiffs to request injunctive relief - argue that they are not required to plead the exact nature of the injunctive relief they are requesting. They claim an injunction may be necessary to address "continuing effects" of Defendants' actions, or to prevent future wrongdoing. Neither of these arguments is sufficient to plausibly allege a right to injunctive relief.

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[10] Dismissal under Rule 12(b)(6) is ordinarily with prejudice unless the court specifically orders dismissal without prejudice. Carter v. Norfolk Community Hosp. Ass'n, Inc., 761 F.2d 970, 974 (4th Cir. 1985). That determination is within the district court's discretion. Id. Given the early posture of this class action, this Report recommends without-prejudice dismissal of certain state consumer protection claims if the addition of specific new class members or additional facts learned in discovery might permit the claim to proceed. However, no party has requested leave to amend.

Plaintiffs seeking injunctive relief must "demonstrate a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 130 (1969). When the anticompetitive actions have ceased - such as with the entry of generic competition - there is usually nothing to enjoin. See United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc., No. 14md02521, 2015 WL 4397396, at *3 (N.D. Cal. July 17, 2015) (dismissing injunctive relief claims because "generic drugs were able to enter the market"); United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Novartis Pharm. Corp., No. 15cv12732, 2017 WL 2837002, at *1 (D. Mass. June 30, 2017), aff'd, 902 F.3d 1 (1st Cir. 2018) (request for injunction mooted by generic entry).

The Retailers do not really distinguish this precedent; rather they insist that at this stage of the proceedings they are not required to specify the exact behavior sought to be enjoined. They argue that courts commonly enter injunctions after unlawful conduct has ceased. See, e.g., California v. Am. Stores Co., 495 U.S. 271, 274-75 (1990) (approving court-ordered divestiture to address effects of unlawful merger). But in this case, the only anticompetitive conduct alleged has been addressed by the entry of multiple generic competitors. CVS Compl. ¶¶ 200-203. And any

continuing effects of the past conduct alleged can be addressed by money damages. CVS Compl. ¶¶ 159-65. While Plaintiffs may not be compelled to specify the exact nature of injunctive relief, they must at least allege some basis to suggest that enjoining future behavior will be a necessary component of full relief. Because money damages capable of calculation will adequately remedy any harm Retailers allege, they have not plausibly alleged a basis for injunctive relief to address continuing harm.

The threat that future similar harm might arise without specifying "which drugs might be involved, or what fraudulent conduct might be undertaken, or which Plaintiffs might buy the drugs at supra-competitive prices" is also insufficient to state a claim for injunctive relief. See In re DDAVP Indirect Purchaser Antitrust Litig., 903 F. Supp. 2d 198, 210-11 (S.D.N.Y. 2012). Such claims are too speculative to provide a basis for the extraordinary remedy of injunction. See In re Plavix Indirect Purchaser Antitrust Litig., No. 1:06-cv-226, 2011 WL 335034, at *4 (S.D. Ohio Jan. 31, 2011) (dismissing claim for injunctive relief based on "yet-to-be-determined reverse payment agreement on some yet unidentified drug").

The Retailers note that Defendants have previously had to defend reverse payment allegations, and imply this pattern distinguishes their claims from others seeking to enjoin future behavior. But the conduct in other reverse payment actions arose

before Actavis was decided, at a time when circuits were split over whether such agreements were even subject to antitrust scrutiny. With the Supreme Court's pronouncement in 2013, the suggestion that Merck or Glenmark is likely to commit some unspecified future antitrust violation with respect to some unnamed future drug requires too much conjecture to survive the Defendants' motion. The court should GRANT the motion to dismiss the Retailers' request for injunctive relief without prejudice.

D. The End Payor Plaintiffs Have Standing and Plausibly Allege Claims under the Laws of Thirty Jurisdictions, but Some Claims Should Be Dismissed for Failing to Allege Elements Required by the Authority They Rely on.

The proposed EPP class asserts four separate categories of claims under the laws of thirty-eight states, the District of Columbia, and Puerto Rico. Defendants challenge these claims on multiple fronts. As explained in the following subsections, this Report recommends GRANTING IN PART and DENYING IN PART Defendants' motion to dismiss all the EPPs' state-law claims. This Report first addresses Defendants' challenges that apply to all categories of claims the EPPs are asserting. It then examines each category separately and by state as necessary. A summary of the recommended dispositions organized by jurisdiction is attached to this Report as Exhibit A. Exhibit B to the Report lists the ten states as to which all claims are recommended to be dismissed, and the claims remaining in the other thirty jurisdictions.

1. The EPPs have alleged anticompetitive conduct sufficient to plausibly state antitrust claims.

First, Defendants argue that all of the EPPs' claims fail for the reasons asserted against the DPPs and Retailers—namely, that the EPP Complaint fails to allege a large and unjustified reverse payment. As described above, this Report concludes that the various complaints have alleged sufficient facts to state a claim under §§ 1 and 2 of the Sherman Act. The EPPs' derivative state claims rest on the same allegations and likewise should not be dismissed on this basis.

2. The EPPs have Article III standing and Defendants' objection to the named class representatives' ability to represent absent class members in other states should be addressed under Rule 23.

In their second broad challenge to the EPP claims, Defendants argue that the EPPs lack standing to assert claims in states where no named plaintiff resides or suffered an injury—that is, paid for allegedly overpriced Zetia or generic ezetimibe. Defendants insist that because the named EPP class representatives themselves cannot assert claims in those states, they lack standing to assert them at this stage in the litigation. The EPPs reply that Defendants are improperly conflating standing issues with Federal Rule of Civil Procedure 23's class certification requirements.

Article III standing requires that claimants demonstrate three elements: injury in fact, causation, and redressability. Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992). Standing

is ordinarily a "threshold jurisdictional question" decided at the outset of a case. See Pye v. United States, 269 F.3d 459, 466 (4th Cir. 2001). However, the Supreme Court has recognized an exception in certain circumstances where class-certification issues are "logically antecedent" to Article III considerations. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 612 (1997); see also Ortiz v. Fibreboard Corp., 527 U.S. 815, 831 (1999).

As the parties' extensive briefing illustrates, courts are split on when exactly that exception applies.[11] At minimum, Amchem appeared to endorse deferring standing questions when class-certification issues are dispositive. See 521 U.S. at 612; see also Winfield v. Citibank, N.A., 842 F. Supp. 2d 560, 574 (S.D.N.Y. 2012). If class certification could affect the standing inquiry (such as by eliminating certain claims or proposed class members), then deferring the latter makes logical sense.[12] Other courts have gone further, explicitly holding that whether named plaintiffs may properly represent nonparty class members with claims under the

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[11] Compare Mem. Opp. Defs.' Mot. Dismiss EPP Compl. 6 & n.7 (ECF No. 188) (citing numerous cases representing a "growing consensus on this question"), with Reply Mem. Supp. Mot. Dismiss EPP Compl. 5 & n.2 (ECF No. 202) (citing numerous decisions among the "majority of cases" that have "rejected EPPs' position").

[12] It may also have some appeal as constitutional avoidance. See In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 154 (E.D. Pa. 2009).

laws of different states "is a question of predominance under Rule 23(b)(3), not a question of 'adjudicatory competence' under Article III." Langan v. Johnson & Johnson Consumer Cos., 897 F.3d 88, 93 (2d Cir. 2018); accord In re Asacol Antitrust Litig., 907 F.3d 42, 48-51 (1st Cir. 2018); Payton v. Cty. of Kane, 308 F.3d 673, 680, 682 (7th Cir. 2002).

I am persuaded by those opinions examining Amchem and Ortiz that this case is one where class certification is "logically antecedent" to Article III standing issues. The named class representatives clearly have standing to press claims in those states where they reside and made or reimbursed purchases. Defendants allege only that they may not, at this stage, assert claims in other states on behalf of those class members who are currently absent. But whether named plaintiffs may properly represent absent class members is exactly the focus of the Rule 23 class certification analysis. The named class representatives are not themselves seeking recovery under the laws of foreign states. They merely allege that all the claims derive from the same source—Defendants' unlawful reverse payment Settlement Agreement. And the proposed class members from those foreign states would, if certified, undoubtedly have standing to pursue claims under those states' laws. This is precisely the situation where class certification is "logically antecedent" to Article III standing. See In re Polyurethane Foam Antitrust Litig., 799 F. Supp. 2d 777,

804-06 (N.D. Ohio 2011); Jepson v. Ticor Title Ins. Co., No. C06-1723, 2007 WL 2060856, at *1-2 (W.D. Wash. May 1, 2007). Closely scrutinizing class standing at this juncture "would render superfluous the Rule 23 commonality and predominance requirements because any case that survived such a strict Article III analysis would by definition present only common issues." Asacol, 907 F.3d at 49.

This Report therefore recommends that the court DENY Defendants' motion to dismiss for lack of standing the EPPs' claims in the following jurisdictions: Alaska, Hawaii, Maine, Nebraska, New Hampshire, Vermont, Puerto Rico, and the District of Columbia. Instead, any standing challenges should be examined during the class certification proceedings.

The remaining challenges to the EPPs' claims can be broken down by category and in many cases by specific states when the laws of those states vary in form or function. This Report analyzes each of these challenges in turn, addressing specific states where necessary.

3. Defendants' motion to dismiss the EPPs' state antitrust claims in nineteen jurisdictions should be denied.

In count one, the EPPs assert antitrust claims under the laws of twenty-four states, the District of Columbia, and Puerto Rico. Defendants moved to dismiss claims in nineteen of these

jurisdictions either for lack of standing or for additional reasons as described below.

a. Indirect purchasers have standing under Puerto Rico law.

Defendants argue that the EPPs cannot maintain a claim under the antitrust laws of Puerto Rico because the jurisdiction has not passed an Illinois Brick repealer statute. In Illinois Brick, the Supreme Court held that indirect purchasers of goods produced by entities engaged in anticompetitive conduct lack standing to bring claims under the federal antitrust laws. Illinois Brick Co. v. Illinois, 431 U.S. 720, 746-47 (1977). Because state antitrust laws are largely modeled off federal law and interpreted accordingly, this effectively limited indirect purchaser antitrust actions in any forum. In response, many states passed so-called Illinois Brick repealer statutes which specifically authorize suits by indirect purchasers under state antitrust laws. The Supreme Court upheld these statutes in California v. ARC America Corp., 490 U.S. 93 (1989).[13]

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[13] The EPPs have not asserted state antitrust claims in the states which follow Illinois Brick, see e.g., Vacco v. Microsoft Corp., 793 A.2d 1048 (Conn. 2002) (holding indirect purchasers lack standing to assert antitrust claims under Connecticut antitrust statute).

Defendants argue that the antitrust laws in Puerto Rico are subject to the Illinois Brick prohibition and therefore do not permit actions by indirect purchasers. The EPPs respond that the Puerto Rico Supreme Court has rejected this limitation, thereby permitting indirect purchaser actions.

Authority on this question is mixed. Compare Aggrenox, 94 F. Supp. 3d at 252 (indirect purchaser actions not permitted), with Rivera-Muniz v. Horizon Lines Inc., 737 F. Supp. 2d 57, 61 (D.P.R. 2010) (indirect purchaser actions permitted). The Aggrenox court reasoned that because the Puerto Rico Antitrust Act is modeled on the Clayton Act, it is subject to the Illinois Brick prohibition in the absence of a clear repealer. See Aggrenox, 94 F. Supp. 3d at 252.

Having reviewed several cases, I agree with the District of Puerto Rico's reasoning in Rivera-Muniz. There the court noted that under Puerto Rico Supreme Court precedent, private antitrust plaintiffs "need not establish anything beyond a factual causal relation between the injury and the violation." Rivera-Muniz, 737 F. Supp. 2d at 61 (quoting Pressure Vessels P.R. v. Empire Gas P.R., 137 D.P.R. 497, 520 (P.R. 1994)). Based on this interpretation of the statute and Puerto Rico's liberal construction of antitrust standing requirements, the court held that "it is immaterial whether plaintiffs are direct or indirect purchasers." Id.; see also Order, Sergeants Benevolent Ass'n

Health & Welfare Fund v. Actavis, PLC, No. 15 Civ. 6549, 2018 WL 7197233, at *23 (S.D.N.Y. Dec. 26, 2018). While true that Pressure Vessels did not explicitly mention Illinois Brick, its expansive standing test is clearly incompatible with Illinois Brick's indirect purchaser prohibition. See Pressure Vessels, 137 D.P.R. at 518-20. This indicates that Puerto Rico's antitrust law is not subject to that prohibition. See Aggrenox, 94 F. Supp. 3d at 252 (acknowledging that a jurisdiction's own courts can "authoritatively interpret their laws as allowing antitrust recovery by indirect purchasers even in the absence of an express Illinois Brick repealer by the legislature").

In light of the Puerto Rico Supreme Court's statements in Pressure Vessels, this Report concludes that indirect purchaser actions are permitted under the antitrust laws of that jurisdiction. Defendants' motion to dismiss the EPPs' claims on this basis should therefore be DENIED.

b. The EPPs' plausibly allege intrastate connection sufficient to meet the requirements of state law.

Defendants argue that the antitrust laws of certain jurisdictions require proof of some degree of intrastate connection. As Defendants characterize the broad allegations in the complaints, they describe only a nationwide pattern of conduct that lacks substantial intrastate action or effects. Defendants argue that failure to make such allegations is fatal to claims in

states requiring this intrastate element. This challenge applies to the antitrust claims in Mississippi, Nevada, New York, North Carolina, South Dakota, Tennessee, West Virginia, Wisconsin, and the District of Columbia.

Cases examining the antitrust laws in these states generally agree that they require allegations of intrastate conduct or effects but define those terms to give the statutes broad scope. See, e.g., In re Broiler Chicken Antitrust Litig., 290 F. Supp. 3d 772, 816 (N.D. Ill. 2017) (finding "substantial" intrastate effects based on allegations of purchases at supracompetitive prices within a state); Aggrenox, 94 F. Supp. 3d at 253 ("[I]t is not obvious why the *intra* state effect of anticompetitive conduct would not be reached by the cited statutes merely because *inter* state conduct predominates."). Defendants' cited cases applying a more rigorous pleading standard are plainly in the minority and are unpersuasive. I rely instead on the ample authority permitting claims to proceed on allegations comparable to those before this court. See, e.g., Aggrenox, 94 F. Supp. 3d at 253 (denying motion to dismiss claims under Mississippi, New York, Tennessee, Wisconsin, and District of Columbia law); Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, 737 F. Supp. 2d 380, 397, 400 (E.D. Pa. 2010) (same in Nevada, North Carolina, and West Virginia); In re Intel Corp. Microprocessor Antitrust Litig., 496 F. Supp. 2d 404, 414 (D. Del. 2007) (same in South Dakota).

This Report concludes that the allegations in the EPPs' Consolidated Complaint sufficiently allege the necessary intrastate connections in each of the challenged jurisdictions. The EPPs allege that Defendants engaged in a nationwide pattern of anticompetitive conduct that resulted in the sale of brand and generic Zetia at supracompetitive prices. They allege that these sales took place in every state where they have asserted claims. The volume of sales and the proceeds realized from the alleged anticompetitive conduct are in the billions of dollars. The court should therefore DENY Defendants' motion to dismiss on the basis of failing to allege intrastate effects.

c. The EPPs' delay in meeting statutory notice requirements does not warrant dismissal.

Defendants next argue that the EPPs failed to comply with provisions in certain state antitrust laws that require private antitrust plaintiffs bringing claims under those laws to file notice of the suit with the state's Attorney General. Defendant moved to dismiss claims in Arizona, Hawaii, Nevada, Rhode Island, and Utah on this ground. The EPPs respond that they have since provided notice in each of those states,[14] that dismissal for late

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[14] Records of the notices may be found in MDL Member Case No. 2:18cv108, ECF Nos. 54-1 to -5. In each instance the EPPs provided the notice only after filing suit.

notice would frustrate the statutes' remedial purposes, and that these notice provisions are inapplicable in federal court under Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co., 559 U.S. 393 (2010).

Again, courts are split on the impact these notice requirements have in federal court. Some give them preclusive effect and dismiss claims when plaintiffs fail to comply. See, e.g., In re Asacol Antitrust Litig., No. 15-cv-12730, 2016 WL 4083333, at *14-15 (D. Mass. July 20, 2016). Others hold that they are merely state procedural rules that do not apply in federal court. See, e.g., Aggrenox, 94 F. Supp. 3d at 253-54. Still others conclude that, even assuming the notice provisions apply in federal court, late or improper notice does not warrant dismissal of the entire claim. See, e.g., In re Aftermarket Filters Antitrust Litig., No. 08C4883, 2009 WL 3754041, at *6 (N.D. Ill. Nov. 5, 2009) (refusing to dismiss Hawaii antitrust claim for failure to comply with notice requirement and noting that "nothing in the statutory scheme suggests that defendants may use the statute as a shield to avoid answering for alleged anti-competitive behavior"); see also Broiler Chicken, 290 F. Supp. 3d at 817 ("Defendants do not cite any authority that late notice requires dismissal, so the Court will not dismiss Plaintiffs' Arizona and Rhode Island antitrust claims on this basis.").

I am persuaded by this last group of cases that dismissal is unwarranted here. Nothing in any of the cited provisions dictates that failure to provide notice requires dismissal. And in this case, the EPPs provided notice. Although notice may have followed initiation of the suit it was provided early in litigation and prior to consolidation or the commencement of any discovery. Dismissing the claims now would be an inefficient and heavy-handed remedy for a relatively minor delay, as to which no one claims prejudice. No Attorney General or other state official has objected to the notice provided or indicated any intent to intervene in the litigation. Moreover, to the extent the statutes prescribe more complex procedural requirements, see, e.g., Haw. Rev. Stat. § 480-13.3, Shady Grove may preclude their operation in federal court, see In re Propranolol Antitrust Litig., 249 F. Supp. 3d 712, 728 (S.D.N.Y. 2017). Accordingly, Defendants' motion to dismiss based on improper notice should be DENIED.

d. The Illinois Antitrust Act class-action bar does not apply in federal court.

Defendants next argue that the EPPs are not authorized to bring their claims under the Illinois Antitrust Act as a class action. They cite to a provision of the Act reading "[N]o person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General."

740 Ill. Comp. Stat. 10/7(2). Some courts have read this provision to bar indirect purchaser class actions under Illinois law from proceeding in federal court. See, e.g., Opana ER, 162 F. Supp. 3d at 723; In re Wellbutrin XL Antitrust Litig., 756 F. Supp. 2d 670, 676-77 (E.D. Pa. 2010). These courts reason that the class action bar is a substantive restriction on the antitrust remedy fashioned by the Illinois legislature. Opana ER, 162 F. Supp. 3d at 723.

The EPPs' response raises two questions: First, does the Illinois Antitrust Act's class-action bar apply in federal court by its own terms? Second, if yes, does Shady Grove dictate that its prohibition on class actions yield to Federal Rule of Civil Procedure 23?

The provision quoted above provides that indirect purchasers may not maintain class actions "in any court of this State." § 10/7(2). By its plain language, that does not include this court. Cf. In re Aggrenox Antitrust Litig., No. 3:14md2516, 2016 WL 4204478, at *5 (D. Conn. Aug. 9, 2016) ("It is not obvious that the formulaic expression 'in any court of this State' appearing in an Illinois statute applies to a federal court in Connecticut."); Piechur v. Redbox Automated Retail, LLC, No. 09cv984, 2010 WL 706047, at *4 (S.D. Ill. Feb. 24, 2010) (concluding that the Southern District of Illinois, "while it may sit *in* the state of Illinois, is not a court *of* the state of Illinois"). But see Wellbutrin XL, 756 F. Supp. 2d at 676 ("Courts outside of Illinois,

however, have read the attorney general restriction to apply to bar indirect purchaser actions in federal court.").

Even if, contrary to its text, the bar applies in this court, I am persuaded by those courts which have concluded that under Shady Grove, Rule 23 governs class actions in federal court and permits the EPPs' suit under the Illinois statute. In Shady Grove, the Supreme Court held that Rule 23 controlled over New York's general class-action bar in federal court. See 559 U.S. at 398-99 (plurality opinion). Writing for a plurality, Justice Scalia concluded that both provisions answered the question whether plaintiffs could pursue their claims via class action. But since Rule 23 was a federal enactment, it was presumed to control the procedural point as long as it was validly enacted. Because the court found it was, its provisions controlled. See id. at 399-400. Justice Stevens concurred but suggested that seemingly procedural state laws may still control if they are "actually ... part of a State's framework of substantive rights or remedies." Id. at 419 (Stevens, J., concurring).

Shady Grove's split opinion has left some questions unresolved. See Mitchell-Tracey v. United General Title Ins. Co., 442 F. App'x 2, 6 (4th Cir. 2011) (suggesting that some state procedural requirements survived Shady Grove). But the bar Defendants seek to apply here is functionally indistinguishable from the bar in Shady Grove. It plainly says that the EPPs may not

maintain their claims in a class action; Rule 23 says just the opposite. See Aggrenox, 2016 WL 4204478, at *5-6 (evaluating the Shady Grove issue and concluding that Rule 23 overrides Illinois class-action bar in federal court); see also Broiler Chicken, 290 F. Supp. 3d at 818 ("[W]hether such plaintiffs may bring a class action does not affect their substantive rights.").

Accordingly, this Report recommends the court DENY Defendants' motion to dismiss the EPPs' Illinois antitrust claims.

e. The EPPs have alleged class members with standing under the Utah Antitrust Act.

Defendants contend that standing to sue under Utah's Antitrust Act is limited to citizens and residents of Utah. See Utah Code Ann. § 76-10-3109(1)(a) (2018). Echoing their broader standing argument, Defendants argue that the EPPs have not alleged that any named plaintiffs are residents of Utah. The EPPs respond that the class definition in their consolidated complaint includes end-payors who purchased Zetia in Utah, thus satisfying the statute. See EPP Compl. ¶ 311 (ECF No. 130 at 88).

For the reasons detailed in the earlier standing discussion,[15] the EPPs' allegations that the class includes Utah residents is sufficient at this stage. See In re Liquid Aluminum Sulfate

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[15] See supra section V.D.2.

Antitrust Litig., No. 16md2687, 2017 WL 3131977, at *28 (D.N.J. July 20, 2017). The court should therefore DENY Defendants' motion to dismiss the EPPs' claims under the Utah Antitrust Act.

f. Antitrust claims - summary of recommended action.

As explained in the foregoing sections, this Report recommends that Defendants' motion to dismiss the EPPs' state antitrust claims be DENIED on all counts. Exhibit A to this Report provides a summary of the recommended disposition for all the EPP claims.

4. Defendants' motion to dismiss the EPPs' state monopolization claims should be denied except as to the claim under California Code section 17200.

In their second count, EPPs assert monopolization claims under the Sherman Act § 2 state analogues of the same twenty-six jurisdictions as in their count one antitrust claims. As with their other claims, EPPs rely on the same allegations set forth by the DPPs and the Retailers. With one exception, Defendants have not raised any specific challenges to these claims or provided any authority to suggest that they should be treated differently. They instead merely reiterate that the state monopolization claims should be dismissed for the same reasons as their federal counterparts.

As discussed above,[16] this Report concludes that Plaintiffs have alleged sufficient facts to state a claim of conspiracy to monopolize under § 2 of the Sherman Act. Therefore, to the extent Defendants' motion seeks dismissal of the corresponding state claims on the same grounds, it should be DENIED.

The sole exception relates to the EPPs' monopolization claim under California law. Defendants argue that under California's Business and Professions Code section 17200 et seq., plaintiffs pursuing a monopolization claim are limited to equitable relief and may not seek damages. See Korea Supply Co. v. Lockheed Martin Corp., 63 P.3d 937, 943 (Cal. 2003). The EPPs essentially conceded this point at oral argument. And on review of the pleadings, the EPPs have not asserted claims for restitution, instead seeking only damages which are expressly precluded under the California statute. Therefore, to the extent the EPPs' monopolization claim under California law seeks damages, it should be DISMISSED with prejudice.

5. The EPPs have stated consumer protection claims in some jurisdictions but have failed to allege required elements in others.

The EPPs' third category of claims arises under the consumer protection laws of twenty-seven states and the District of

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[16] See supra section V.D.3.d.

Columbia. Defendants argue that claims in twenty-five of these jurisdictions should be dismissed either for lack of standing or for specific reasons detailed below. As explained above, this Report concludes that Defendants' Article III standing challenge is better addressed at class certification and therefore recommends the court DENY their motion to dismiss on that ground. The remaining challenges will be addressed by category, addressing specific states as necessary. Note that in some instances claims in a particular state may be recommended for dismissal on some grounds but not others. The summary at the end of this subsection will identify those state claims recommended for dismissal on any ground and is reflected in Exhibit A.

a. Indirect purchasers may assert consumer protection claims under Illinois and Missouri law in federal court.

Defendants' assertion that indirect purchaser class actions are not permitted under Illinois' consumer protection statute is premised on their analogous challenge to the EPPs' antitrust claims under Illinois law.[17] They argue that, assuming indirect purchasers are barred from pursuing antitrust class actions, permitting them to do so under the consumer protection statute would undermine

[17] See supra section V.D.3.d.

that policy determination. See In re Flonase Antitrust Litig. (Flonase II), 692 F. Supp. 2d 524, 539 (E.D. Pa. 2010).

As explained above, however, Illinois' class-action bar does not prevent the EPPs from maintaining their class action suit in federal court under the Illinois Antitrust Act. Furthermore, to the extent the EPPs have stated an independent claim for violation of Illinois' consumer protection statute, they are entitled to seek remedies by the means available under that law. See Siegel v. Shell Oil Co., 480 F. Supp. 2d 1034, 1048-49 (N.D. Ill. 2007) (recognizing that actionable conduct under the Illinois Consumer Fraud Act may also be covered by the Illinois Antitrust Act). Furthermore, the Illinois CFA has broad scope by its own terms and has no corresponding class-action limitation. See 815 Ill. Comp. Stat. 505/2 (prohibiting "unfair methods of competition" in harmony with the FTC Act); id. § 505/10a. Laughlin v. Evanston Hosp., 550 N.E.2d 986 (Ill. 1990), does not withdraw the EPPs' present claims from that coverage as Defendants' claim. See Siegel, 480 F. Supp. 2d at 1046-49. And allowing the claims under the CFA does not circumvent any substantive policy, because Illinois does not bar indirect purchaser antitrust claims. Accordingly, the EPPs' class action is not categorically barred under Illinois' consumer protection laws and this Report recommends that Defendants' motion to dismiss on this basis be DENIED.

Similarly, Defendants argue that because Missouri has not passed an Illinois Brick repealer, permitting the EPPs to bring an indirect purchaser action under Missouri's consumer protection statute "would provide an end-run around the state's prohibition of antitrust claims by indirect purchasers." In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 702 (E.D. Pa. 2014).

In response, the EPPs cite to the Missouri Supreme Court's decision in Gibbons and subsequent cases applying it. Gibbons rejected any direct privity requirement for suits under Missouri's consumer protection statute and seemed to endorse indirect purchaser actions. See Gibbons v. J. Nuckolls, Inc., 216 S.W.3d 667, 669-70 (Mo. 2007). Federal courts applying Gibbons have followed suit. See, e.g., In re Packaged Seafood Prods. Antitrust Litig., 242 F. Supp. 3d 1033, 1079 (S.D. Cal. 2017) ("This Court joins the majority of our sister courts and concludes that Illinois Brick does not bar indirect-purchaser claims under the MMPA."). Defendants' sole post-Gibbons case to the contrary rests on speculative reasoning and goes against the majority view. See Suboxone, 64 F. Supp. 3d at 702 (reasoning that Gibbons should not apply to claims premised on antitrust-type injury). Because Gibbons appears to answer the Defendants' indirect purchaser objection, this Report recommends the court DENY Defendants' motion on this basis.

b. The EPPs' allegations do not satisfy the deception and/or reliance requirements in some state consumer protection statutes.

Defendants challenge the EPPs' claims in eleven jurisdictions for failure to specifically allege deceptive conduct by Defendants or reliance by the EPPs. Defendants' broad contention is that the EPPs have alleged only antitrust violations that fail to satisfy the required elements under the laws of these jurisdictions, many of which are specifically directed at deceptive or fraudulent commercial conduct. The EPPs respond that many of these statutes prohibit "unfair" or "unconscionable" conduct and should be construed broadly regardless of their exact language.

One recurring statutory pattern among several of these jurisdictions is the prohibition of "unfair methods of competition" (or similar language) and incorporation of a Federal Trade Commission ("FTC") Act harmonization provision. The latter is important because the Supreme Court has construed the FTC Act, on which many state consumer protection laws are modeled, to broadly cover unfair trade practices. See Ind. Fed'n of Dentists, 476 U.S. at 454 (recognizing that "unfairness" under the FTC Act encompasses "practices that violate the Sherman Act and the other antitrust laws"). Thus, state laws with equivalent "unfairness" language and an FTC Act harmonization provision can safely be assumed to have similarly broad scope. Other states, however, target a narrower range of conduct not included in the EPPs claims

of anticompetitive collusion. This Report's recommendations on this issue are as follows:

- **Arizona**. Arizona's consumer protection law, as amended in 2013, prohibits "unfair" practices and contains an FTC Act harmonization provision. Ariz. Rev. Stat. Ann. § 44-1522. Defendants' sole cited case predates the addition of the "unfairness" language, which substantially broadens the statute's scope. Cf. Sheet Metal Workers, 737 F. Supp. 2d at 404. The court should DENY Defendants' motion to dismiss the Arizona claims on this basis.
- **Arkansas.** Arkansas's consumer protection laws prohibit "[d]eceptive and unconscionable trade practices," Ark. Code Ann. § 4-88-107, language that Arkansas courts construe broadly, see Baptist Health v. Murphy, 226 S.W.3d 800, 811 (Ark. 2006); see also Packaged Seafood Prods., 242 F. Supp. 3d at 1072. However, the reliance requirement in section 4-88-113(f)'s private cause of action is incompatible with the allegations in the EPPs' Complaint. The EPPs cannot plausibly claim to have "relied" on any of the Defendants' acts which produced the elevated pricing of Zetia or ezetimibe. Coupled with the absence of broadly construed "unfairness" language in the statute, I conclude that the EPPs have not sufficiently alleged a violation of Arkansas's consumer protection laws.

The EPPs' claims should therefore be DISMISSED without prejudice.

- **District of Columbia.** Washington D.C.'s consumer protection laws prohibit "unfair" trade practices and include both an expansive list of enumerated examples and an FTC Act harmonization provision. D.C. Code §§ 28-3901, -3904. Courts regularly permit claims under D.C. law premised on anticompetitive conduct. See, e.g., In re Processed Egg Prods. Antitrust Litig., 851 F. Supp. 2d 867, 898-99 (E.D. Pa. 2012). The case of Williams v. Purdue Pharma Co., 297 F. Supp. 2d 171 (D.D.C. 2003), cited by Defendants, is distinguishable on its facts and because it considered only the statute's prohibition on "deceptive" conduct without addressing unfairness. Defendants' motion to dismiss the D.C. consumer protection claims should be DENIED.
- **Idaho.** Idaho prohibits unfair methods of competition and aligns its consumer protection statute with the FTC Act. See Idaho Code §§ 48-603, -604. I agree with those cases that have permitted claims premised on anticompetitive conduct to proceed under this statute. See, e.g., Intel Corp., 496 F. Supp. 2d at 418. The motion to dismiss the EPPs' Idaho consumer protection claims should be DENIED.
- **Maine.** Maine's consumer protection statute covers "unfair methods of competition" and includes an FTC Act harmonization

provision. Me. Stat. tit. 5, § 207. It encompasses harms premised on antitrust violations. See In re New Motor Vehicles Canadian Export Antitrust Litig., 350 F. Supp. 2d 160, 186-87, 187 n.40 (D. Me. 2004). Defendants' motion to dismiss the Maine consumer protection claims should therefore be DENIED.

- **Michigan.** Michigan's consumer protection law refers to the FTC Act but does not contain an express harmonization provision. See Mich. Comp. Laws § 445.911(3). The enumerated unlawful practices in section 445-903 are primarily directed at deceptive practices, and several courts have dismissed claims under Michigan law for failure to allege fraud or deception. See Packaged Seafood Prods., 242 F. Supp. 3d at 1076-77. The EPPs point to Solodyn, which held that anticompetitive conduct could be actionable under an anti-price-gouging provision. In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2015 WL 5458570, at *17 (D. Mass. Sept. 16, 2015). But that case appears to be an outlier on this point, and other cases permitting claims based on allegations of anticompetitive conduct have made specific findings of deceptive conduct. See, e.g., Suboxone, 64 F. Supp. 3d at 700-01 (concluding that Michigan consumer protection statute requires proof of "intent to deceive" and finding element satisfied by allegations that defendants fabricated a drug safety issue).

Because the EPPs have not sufficiently alleged deceptive conduct, their consumer protection claims under Michigan law should be DISMISSED without prejudice.

- **Minnesota.** The Minnesota consumer protection law applies only to "conduct that is deceptive or fraudulent, as opposed to merely anticompetitive." Niaspan, 42 F. Supp. 3d 735, at 760. Courts permitting claims of anticompetitive conduct under Minnesota Code section 325F.69(1) have relied on allegations of deception or fraud. See id. (collecting examples). Because the EPPs have made not made such allegations here, their consumer protection claims under Minnesota law should be DISMISSED without prejudice.

- **New York.** New York's consumer protection law does not include broad "unfairness" language but is instead directed only at deceptive or misleading practices. See In re Digital Music Antitrust Litig., 812 F. Supp. 2d 390, 410 (S.D.N.Y. 2011) (examining state court authority). It does not cover "anticompetitive conduct that is not premised on consumer deception." Id. (quoting Leider v. Ralfe, 387 F. Supp. 2d 283, 295 (S.D.N.Y. 2005)). Because the allegations here do not reflect consumer-oriented deception by any Defendants, the EPPs' consumer protection claims under New York law should be DISMISSED without prejudice.

- **Rhode Island.** Rhode Island's consumer protection statute contains broad unfairness language and an FTC Act harmonization provision. 6 R.I. Gen. Laws. Ann. §§ 6-13.1-2, -3. The Rhode Island Supreme Court has also endorsed a broad reading of the law. See Ames v. Oceanside Welding & Towing Co., 767 A.2d 677, 681 (R.I. 2001). Courts applying the Ames standard have permitted claims under the state's consumer protection statute premised on anticompetitive conduct. See, e.g., In re Effexor Antitrust Litig., No. 3:11cv5661, 2018 WL 6003893, at *22 (D.N.J. Nov. 15, 2018) (permitting claim based on anticompetitive conduct "which resulted in consumers purchasing Effexor XR at a premium rate"). In light of the Rhode Island Supreme Court's opinion, This Report recommends that the court DENY Defendants' motion to dismiss the EPPs' Rhode Island consumer protection claims.
- **South Dakota.** South Dakota's consumer protection law specifically requires proof of deceptive conduct causing consumer harm. See DDAVP, 903 F. Supp. 2d at 229. The conduct complained of here—an unlawful pay-for-delay settlement agreement—may have harmed consumers, but it did not defraud or mislead them. The EPPs have included allegations in their complaint that Defendants engaged in inequitable conduct before the Patent and Trademark Office, but those claims are ancillary to the alleged anticompetitive practices central to

the complaint. The EPPs have cited no authority supporting a broader scope for South Dakota law. Their South Dakota consumer protection claims should therefore be DISMISSED without prejudice.

- **Vermont.** The Vermont Consumer Fraud Act prohibits "unfair methods of competition" and contains an FTC Act harmonization provision. Vt. Stat. Ann. 9, § 2453 (West 2018). The statute should be liberally construed "to have as broad a reach as possible in order to best protect consumers against unfair trade practices." Elkins v. Microsoft Corp., 817 A.2d 9, 13 (Vt. 2002). In Elkins the court explicitly held that indirect purchasers could bring antitrust claims under the civil penalty provision of the VCFA. Id. at 20. Propranolol, cited by Defendants, seemingly ignored the "unfair methods of competition" prong of the Vermont statute in dismissing a claim for failure to show a deceptive act. See 249 F. Supp. 3d at 729. Similarly, Aggrenox, which suggested that the VCFA did not reach antitrust conduct, seems to have overlooked Elkins. See Aggrenox, 2016 WL 4204478, at *9 (further concluding that plaintiffs were not "consumers" under the VCFA). The EPPs' citation to Vermont caselaw is more persuasive. This Report therefore recommends the court DENY Defendants' motion to dismiss the EPPs' Vermont consumer protection claims on this ground.

c. The EPP's claims of anticompetitive conduct are not actionable under some states' consumer protection laws.

Defendants next argue that "pure antitrust" violations, as they have characterized the EPPs' allegations, are not cognizable claims under the consumer protection laws of several states. After reviewing the respective state laws and cases applying them, this Report recommends the court DENY Defendants' motion to dismiss the EPPs' consumer protection claims under the laws of Illinois and West Virginia. See Packaged Seafood Prods., 242 F. Supp. 3d at 1087-88 (sustaining price-fixing claim under West Virginia's consumer protection statute after highlighting importance of FTC Act harmonization provision added in 2015); Seigel, 480 F. Supp. 2d at 1043-49 (permitting antitrust-type claim to proceed under Illinois Consumer Fraud Act).

The court should DISMISS the EPPs' consumer protection claims with prejudice in each of the remaining challenged states for the reasons and on the authority cited:

- **Idaho**. See State ex rel. Wasden v. Daicel Chem. Indus., Ltd., 106 P.3d 428, 433-35 (Idaho 2005) (limiting Idaho consumer protection statute to "unconscionable 'sales conduct' that is direct at the consumer"); see also Polyurethane Foam, 799 F. Supp. 2d at 786.
- **Kansas**. "Despite the [Kansas Consumer Protection Act's] seemingly broad language, the Supreme Court of Kansas has

distinguished between consumer harms redressable thereunder and pricing harms governed by the Kansas antitrust statute." In re Chocolate Confectionary Antitrust Litig., 602 F. Supp. 2d 538, 584 (M.D. Pa. 2009) (citing Equitable Life Leasing Corp. v. Abbick, 757 P.2d 304, 306-08 (Kan. 1988)).

- **Oregon**. Courts typically dismiss claims under Oregon's consumer protection law that lack allegations of deceptive conduct, as is the case here. See, e.g., In re Lidoderm Antitrust Litig. (Lidoderm II), 103 F. Supp. 3d 1155, 1170-71 (N.D. Cal. 2015); see also In re Dynamic Random Access Memory (DRAM) Antitrust Litig., 516 F. Supp. 2d 1072, 1115-16 (N.D. Cal. 2007) (holding that plaintiffs could not state a price-fixing claim under Oregon's consumer protection law); cf. Packaged Seafood Prods., 242 F. Supp. 3d at 1083-84 (sustaining claim under Oregon law where plaintiffs "plausibly allege[d] affirmative misrepresentations").
- **Tennessee**. "[P]laintiffs cannot bring claims based on anticompetitive conduct under the Tennessee Consumer Protection Act." In re Flonase Antitrust Litig. (Flonase I), 610 F. Supp. 2d 409, 417 (E.D. Pa. 2009) (citing Sherwood v. Microsoft Corp., No. M2000-01850-COA-R9-CV, 2003 WL 21780975, at *110 (Tenn. Ct. App. July 31, 2003)); see also Bennett v. Visa USA, Inc., 198 S.W.3d 747, 754-55 (Tenn. Ct. App. 2006)

(discussing the significance of TCPA's lack of "unfair competition" language).

- **Utah**. Although Utah's Consumer Sales Practices Act contains an FTC Act harmonization provision, it lacks the broad "unfair competition" language on which federal courts have relied in extending the latter to cover price-fixing. See DRAM, 516 F. Supp. 2d at 1117. The Utah CSPA's broadest provision covers "unconscionable" conduct, which Utah courts have interpreted using contract law definitions. See New Motor Vehicles, 350 F. Supp. 2d at 203-05 (surveying state court decisions). The EPPs have not pled sufficient facts to state a claim under this standard of unconscionability.

d. The EPPs have pled sufficient intrastate connection.

Defendants argue that the EPPs have not pled sufficient intrastate conduct or effects under the consumer protection laws of New Hampshire, New York, or North Carolina. As with state antitrust laws requiring intrastate allegations, see supra section V.D.3.b, the clear trend is to broadly construe these "intrastate" pleading requirements to include allegations of causing substantial harm to in-state residents. See, e.g., Suboxone, 64 F. Supp. 3d at 702 (sustaining claim under New York consumer protection statute on the basis of overcharges that occurred in the state); DDAVP, 903 F. Supp. 2d at 231 (concluding that allegations of in-state sales at supracompetitive prices satisfy

the intrastate requirement); LaChance v. U.S. Smokeless Tobacco Co., 931 A.2d 571, 578 (N.H. 2007) (holding that allegations state a claim under New Hampshire Consumer Protection Act if they "encompass conduct which was part of trade or commerce that had direct or indirect effects on" state citizens). Because the EPPs have alleged a nationwide pattern of conduct that resulted in consumers in each of the challenged jurisdictions purchasing ezetimibe at elevated prices, they have pled sufficient intrastate connections under those consumer protection statutes. The court should therefore DENY Defendants' motion to dismiss the New Hampshire, New York, and North Carolina consumer protection claims on this basis.

e. The EPPs are not "Consumers" as defined by some state consumer protection laws.

Every jurisdiction defines "consumer" for the purposes of setting out the scope of its consumer protection laws and the persons or entities entitled to sue under those laws. Defendants argue that the EPPs as a class are not proper plaintiffs under the laws of eight jurisdictions. These jurisdictions, according to Defendants, do not provide a right of action to municipal corporations or health plans that reimburse members for private purchases.

The EPPs respond that the class definition is broad enough to encompass both third-party payors and individual purchasers.[18] However, the current named class representatives do not include any individuals and, as third-party payors, they would be unable to effectively represent individuals on these particular claims. This is because, as explained below, the current named plaintiffs cannot plausibly allege a right to recover under those state consumer protection laws that exclude third-party payors from their definition of "consumer." The current named class representatives therefore lack any incentive to litigate those claims.[19] In such circumstances, dismissal is proper even against plaintiffs purporting to be acting in representative capacity. See Asacol, 907 F.3d at 49 ("[T]he pertinent question is: Are the

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[18] The class definition in the EPPs' Consolidated Complaint reads:

> All persons and entities in the Indirect Purchaser States that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Zetia or its AB-rated generic equivalents in any form, other than for resale, from December 6, 2011 through and until the antitcompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

EPP Compl. ¶ 311 (ECF No. 130 at 83).

[19] This nuance in state consumer protection laws distinguishes this issue from, for example, the question of whether the EPPs can assert an antitrust claim in Utah even though no named class representative resides there. See supra section V.D.3.e. Analogous antitrust laws in the named representatives' respective states do not restrict third-party payors from bringing claims.

differences that do exist [between the claims of the class members and those of the class representative] the type that leave the class representative with an insufficient personal stake in the adjudication of the class members' claims?"). Accordingly, this court should not permit the EPPs' claims to go forward simply because the class may include individuals in the challenged states.

The EPPs are proper plaintiffs under Virginia's consumer protection law, which (1) provides a right of action to any person (including a legal entity) that suffers a loss caused by a violation of the statute, (2) covers fraudulent acts or practices committed by a supplier "in connection with a consumer transaction," and (3) defines a consumer transaction as one that involves goods purchased primarily for personal, family, or household purposes. See Va. Code Ann §§ 59.1-198, -200. Drawing reasonable inferences in their favor, the EPPs plausibly allege that Defendants violated the statute in connection with the commercial sale of overpriced ezetimibe and that the EPPs, responsible for reimbursement of the purchase prices in those transactions, suffered a loss as a result. The court should therefore DENY Defendants' motion to dismiss the EPPs' consumer protection claim under Virginia law.

The presently named EPPs cannot, however, invoke the consumer protection laws of the other seven jurisdictions challenged on this basis. As health and benefit plans, they do not actually make

purchases—rather, they reimburse their members or pharmacies for the costs of Zetia or ezetimibe purchases when their members fill prescriptions. That transaction is strictly commercial, carried out as a matter of contract between the named EPPs and their premium-paying members.[20] See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig., No. 18-MD-2819, 2018 WL 5928143, at *12 (E.D.N.Y. Nov. 13, 2018). And contrary to the EPPs' suggestion, the mere fact that the underlying transaction (that is, the drug purchase) is for "personal, family, or household use," as most of the laws at issue require, does not extend a right of action to third-party payors which reimburse those payments as part of a separate insurance obligation. This Report therefore recommends the court DISMISS the EPPs' consumer protections claims without prejudice in the following jurisdictions:

- **District of Columbia**. D.C.'s consumer protection statute is intended to reach "the ultimate retail transaction between the final distributor and the individual member of the consumer public." Adam A. Weschler & Son, Inc. v. Klank, 561 A.2d 1003, 1005 (D.C. 1989). Secondary reimbursement transactions are outside the ambit of the statute. See

[20] It is also not unique to Zetia, ezetimibe, or any particular drug; the EPPs simply reimburse consumers for some portion of all qualified healthcare costs.

Lidoderm II, 103 F. Supp. 3d at 1164-65 (dismissing health plan's consumer protection claim under D.C. law).

- **Kansas.**[21] Kansas law narrowly defines "consumer" in terms of individuals or natural persons, excluding the named EPP class representatives. See Kan. Stat. Ann. § 50-624; Solodyn, 2015 WL 5458570, at *17.

- **Maine.** Although Maine's consumer protection law defines "person" to include legal entities, it limits private actions to persons who "purchase[] or lease[] goods ... primarily for personal, family, or household purposes." Me. Stat. tit. 5, §§ 206, 213. This category does not include the named EPP class representatives.

- **Massachusetts.** Plaintiffs engaged in trade or commerce, a group that includes the third-party payor EPPs, must proceed under section 11 of the Massachusetts Consumer Protection Act. See Lidoderm I, 74 F. Supp. 3d at 1084-85 (concluding that municipality and welfare plan that purchased and/or reimbursed purchases of prescription drugs were engaged in "trade or commerce" within meaning of MCPA). However, section 11 bars indirect purchaser claims. Id. at 1086.

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[21] This Report recommends dismissing with prejudice the EPPs' consumer protection claim in Kansas on another basis. See supra section V.D.5.c.

- **Missouri**. Private actions under Missouri's consumer protection law are limited to persons who purchase or lease merchandise "primarily for personal, family or household purposes." Mo. Rev. Stat. § 407.025. Third-party payors like health plans may not assert claims under this provision. See Asacol, 2016 WL 4083333, at *12.
- **Rhode Island**. Only persons who purchase goods "for personal, family, or household purposes" may sue under Rhode Island's consumer protection law. R.I. Gen. Laws § 6-13.1-5.2; see also In re Effexor Antitrust Litig., 337 F. Supp. 3d 435, 467 (D.N.J. 2018).
- **Vermont**. See Aggrenox, 2016 WL 4204478, at *9 ("The fact that Humana's members are consumers, and that Humana co-purchases or reimburses for consumer products that its members use, does not make Humana a consumer of those products.").

f. The EPPs have substantially complied with statutory notice provisions.

Defendants argue that the EPPs' consumer protection claims in Massachusetts and West Virginia should be dismissed for failure to comply with the notice provisions in those states' laws. As explained above, it is unclear whether these provisions even apply in federal court, let alone demand dismissal for noncompliance. See supra section V.D.3.c. The case for applying them in the consumer protection context is stronger than in the antitrust

context because the required notice is to the defendant (in the form of a demand letter and cure opportunity), rather than to the state attorney general.[22] However, neither provision requires dismissal in this case.

The Massachusetts notice provision only applies to claims under section 9 of the state's consumer protection act. Section 11, under which the EPPs must proceed here, has no notice requirement. As for West Virginia, Defendants' characterization of the notice provision as a rigid pre-suit requirement ignores the language added by 2015 amendment that explicitly contemplates post-filing demand letters. See id. (specifying twenty days from receipt of notice to make a cure offer "but ten days in the case a cause of action has already been filed"). Waters v. Electrolux Home Prods., Inc., 154 F. Supp. 3d 340 (N.D.W. Va. 2015), a post-amendment case cited by Defendants, is factually distinguishable. There the plaintiffs never provided a written demand letter specifying the cure opportunity, but merely relied on their complaint to give notice. Id. at 354. Here, by contrast, the EPPs

[22] See Mass. Gen. Laws ch. 93A, § 9; W. Va. Code § 46A-6-106(c).

provided separate written notice with a ten-day cure offer window, as section 46A-6-106(c) requires.[23]

For these reasons, this Report recommends the court DENY Defendants' motion to dismiss the EPPs' Massachusetts and West Virginia consumer protection claims on this basis.

g. Florida's heightened pleading standard does not apply in this case.

Defendants assert that the EPPs must plead their Florida consumer protection claims with particularity under the heightened pleading standard of Federal Rule of Civil Procedure 9(b). See, e.g., Suboxone, 64 F. Supp. 3d at 699-700. However, the EPPs are proceeding under the statute's "unfair methods of competition" prong which encompasses antitrust violations and avoids the heightened pleading standard applicable to the fraud prong. See Processed Egg Prods., 851 F. Supp. 2d at 900. The court should therefore DENY Defendants' motion to dismiss on this basis.

h. Tennessee's class-action bar does not apply in federal court.

Defendants contend that Tennessee's consumer protection statute does not permit class actions. See Tenn. Code Ann. § 47-18-109(a)(1) ("Any person who suffers an ascertainable loss ...

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[23] Record of this notice may be found in MDL Member Case No. 4:18cv108, ECF No. 54-6. The EPPs sent the letter slightly less than two months after filing suit.

may bring an action individually to recover actual damages."). The EPPs argue that to the extent this statute prohibits class actions, it must yield to Rule 23 under Shady Grove.

This Report has already recommended dismissal of the EPPs' Tennessee consumer protection claims on alternative grounds.[24] The Shady Grove issue remains unsettled, but as discussed above, these procedural restrictions appear to conflict with Rule 23. This Report therefore recommends the court DENY Defendants' motion to dismiss the EPPs' Tennessee consumer protection claims on this basis.

i. Consumer protection claims - Summary of recommended action.

For the foregoing reasons, this Report recommends that the court GRANT Defendants' motion and DISMISS the EPPs' consumer protection claims in the following jurisdictions: Arkansas, Idaho, Kansas, Maine, Massachusetts, Michigan, Minnesota, Missouri, New York, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, and the District of Columbia. For claims which may be affected by the addition of tag along cases, the definition of the class, or more specific evidence of deception not yet pled, the Report recommends without-prejudice dismissals as noted. The court

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[24] See supra section V.D.5.c.

should DENY Defendants' motion to dismiss the consumer protection claims in the remaining jurisdictions. A summary of the recommended disposition of all the EPP claims in included as Exhibit A.

6. The EPPs' state unjust enrichment claims should be dismissed in some jurisdictions and allowed in others.

Finally, the EPPs assert common-law unjust enrichment claims under the laws of thirty-seven states and the District of Columbia. Defendants renew their general objections to these claims and assert additional grounds for dismissal applicable to some or all. As with the previous sections, this Report will address each dismissal argument by category and by state as necessary. A summary follows and is reflected in Exhibit A.

a. The EPPs' Complaint satisfies the Rule 8 pleading requirement for unjust enrichment.

Defendants' initial challenge, applicable to every jurisdiction where the EPPs have asserted unjust enrichment claims, contends that the EPPs have not adequately pled their claims under Rule 8. Defendants argue that the EPPs have only "pled" unjust enrichment claims by alleging facts aimed at antitrust violations and then stating, in conclusory fashion, that such facts are also actionable as unjust enrichment. Cf. Aggrenox, 94 F. Supp. 3d at 254-56 (dismissing all state unjust enrichment claims without prejudice for failure to satisfy Rule 8). The EPPs argue in response that their Complaint broadly satisfies the elements for state unjust enrichment claims, which are "materially

the same throughout the United States." Singer v. AT&T Corp., 185 F.R.D. 681, 692 (S.D. Fla. 1998).

At minimum, an unjust enrichment plaintiff must ordinarily allege receipt of a benefit by the defendant at plaintiff's expense and "that it would be inequitable or unjust for defendant to accept and retain the benefit." Flonase II, 692 F. Supp. 2d at 541. Examining the allegations in the EPPs' Complaint as a whole and drawing all reasonable inferences in their favor, I find that they have adequately pled the necessary elements of common-law unjust enrichment. Cf. In re Automotive Parts Antitrust Litig., 29 F. Supp. 3d 982, 1014-15 (E.D. Mich. 2014) (declining to dismiss all unjust enrichment claims for conclusory pleading because "the Court does not read these allegations in isolation, but in light of all of the factual allegations in the complaints"). The EPPs allege that Defendants unlawfully maintained monopoly pricing on ezetimibe products and unjustly reaped extraordinarily increased profits at the expense of the EPPs, who paid supracompetitive prices for those products for five years. Although the portion of the Complaint asserting unjust enrichment is somewhat conclusory, it incorporates by reference the extensive factual allegations that precede it. EPP Compl. ¶ 360 (ECF No. 130 at 105). Requiring recharacterization of every allegation into an unjust enrichment framework would create needlessly repetitive pleading. And conclusory pleading is to some degree unavoidable, given that an

element of unjust enrichment is the character of the defendants' actions, not simply the actions themselves. This Report therefore recommends that Defendants' motion to dismiss all unjust enrichment claims for inadequate pleading be DENIED.

b. The EPPs cannot rely on common-law unjust enrichment to circumvent Illinois Brick.

Several of the jurisdictions in which the EPPs assert unjust enrichment claims follow the Illinois Brick rule precluding antitrust claims by indirect purchasers. Defendants argue that allowing unjust enrichment claims premised on antitrust violations in these jurisdictions circumvents state policy against indirect purchaser antitrust actions.

Although the EPPs cite some authority in their favor, the clear majority view favors Defendants on this point. See, e.g., Lidoderm I, 74 F. Supp. 3d at 1088-90 ("I agree with the majority of courts who have directly addressed this issue and find that the EPPs cannot circumvent the Illinois Brick prohibition absent authority from the courts of those states that would allow unjust enrichment claims to proceed."); DDAVP, 903 F. Supp. 2d at 231-33. The EPPs' few cited cases disagree with the general proposition but offer little in the way of state authority to contradict it.[25]

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[25] This Report rejected similar Illinois Brick-circumvention challenges to consumer protection claims in some jurisdictions,

Accordingly, this court should DISMISS with prejudice the EPPs' unjust enrichment claims in the following states: Alaska, Arkansas, Colorado, Connecticut, Maryland, Massachusetts, Missouri, Montana, and South Carolina.

c. The EPPs' allegations do not satisfy the direct benefit requirement under some states' unjust enrichment laws.

In some states, plaintiffs pursuing unjust enrichment claims must demonstrate that they conferred the unjust benefit directly on the defendant. Because the EPPs as a class did not deal directly with any Defendant, they may not advance an "indirect" unjust enrichment theory in states following this rule. The court should therefore DISMISS with prejudice the EPPs' unjust enrichment claims in the following states on the authority cited:

- **Florida**. See Kopel v. Kopel, 229 So. 3d 812, 818 (Fla. 2017) ("[T]o prevail on an unjust enrichment claim, the plaintiff must directly confer a benefit to the defendant.").

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but did so because state authority made clear that those claims were independently actionable or otherwise not barred by Illinois Brick. By contrast, little if any state authority exists to support common-law unjust enrichment claims by indirect purchasers alleging antitrust injury in jurisdictions following Illinois Brick.

- **Idaho**. See Lincoln Land Co. v. LP Broadband, Inc., 408 P.3d 465 (Idaho 2017); Stevenson v. Windermere Real Estate/Capital Grp., Inc., 275 P.3d 839, 842-44 (Idaho 2012).
- **Michigan**. See Fenerjian v. Nongshim Co., 72 F. Supp. 3d 1058, 1086-88 (N.D. Cal. 2014) (analyzing state cases and concluding that indirect unjust enrichment claims are not permitted under Michigan law). The EPPs' cited cases find less support in state authority.

Defendants challenge claims in five additional states, which they claim require a direct benefit to impose unjust enrichment liability. However, this Report concludes that indirect unjust enrichment claims are permitted in those states. The court should therefore DENY Defendants' motion to dismiss the EPPs' unjust enrichment claims in the following states on the authority noted:

- **Kansas**. See Automotive Parts, 29 F. Supp. 3d at 1019-20 ("[T]here is no element [in Kansas unjust enrichment law] requiring that the benefit flow directly from the plaintiff to the defendants."). Cases reaching the opposite conclusion frequently rely on the Kansas Supreme Court's decision in Haz-Mat Response, Inc. v. Certified Waste Servs. Ltd., 910 P.2d 839 (Kan. 1996). But Haz-Mat Response involved complicated factual issues and did not conclusively hold that indirect unjust enrichment claims cannot proceed under Kansas law. The case examined whether a plaintiff subcontractor

hired by a prime contractor to do work on the defendant property owner's property could recover from the property owner via unjust enrichment when the prime contractor failed to pay the subcontractor. The court held that on the facts of the case, plaintiffs had not demonstrated "special circumstances" showing the defendant inequitably retained a benefit from the plaintiff when it reasonably should have known the plaintiff expected to be compensated. See id. at 847-48.

- **Maine**. See In re Opana ER Antitrust Litig., No. 14C10150, 2016 WL 4245516, at *2-3 (N.D. Ill. Aug. 11, 2016) (sustaining indirect unjust enrichment theory and observing that "[t]he critical inquiry is whether the Defendants received a benefit at EPPs' expense").
- **New York**. Plaintiffs need not plead "direct dealing" or an "actual substantive relationship" with the defendant. The only requirement is that the connection between plaintiff and defendant not be "too attenuated." See Sperry v. Crompton Corp., 863 N.E.2d 204, 215-16 (N.Y. 2007).
- **North Carolina**. See Processed Egg Prods., 851 F. Supp. 2d at 930-32 (concluding that North Carolina Supreme Court precedent embraces an "expansive view of unjust enrichment and the role or particulars of the conferral of a benefit

element" (citing Embree Const. Grp., Inc. v. Rafcor, Inc., 411 S.E.2d 916 (N.C. 1992)).

- **North Dakota**. See Automotive Parts, 29 F. Supp. 3d at 1025 (sustaining indirect purchaser unjust enrichment claim).

d. The EPPs may plead unjust enrichment in the alternative.

Finally, Defendants claim that the EPPs' unjust enrichment claims fail in Alabama, Hawaii, and Massachusetts because their Complaint alleges adequate remedies at law. But Rule 8 explicitly permits pleading in the alternative, and the EPPs' Consolidated Complaint does just that. Fed. R. Civ. P. 8(d)(2); EPP Compl. ¶ 361 (ECF No. 130 at 105. The court should therefore DENY Defendants' motion to dismiss on this basis.

e. Unjust Enrichment - Summary of recommended action.

For the foregoing reasons, this Report recommends the court GRANT Defendants' motion and DISMISS with prejudice the EPPs' unjust enrichment claims in Alaska, Arkansas, Colorado, Connecticut, Florida, Idaho, Maryland, Massachusetts, Michigan, Missouri, Montana, and South Carolina. The court should DENY Defendants' motion to dismiss the EPPs' unjust enrichment claims in the remaining jurisdictions. Exhibit A summarizes the recommended disposition for all of the EPP claims.

Conclusion

For the reasons described above, the court should DENY the Defendants' Motion to Dismiss the DPPs' Consolidated Complaint (ECF No. 157). The court should GRANT IN PART and DENY IN PART the Defendants' Motion to Dismiss the Retailers Complaints (ECF No. 160), denying the motion with respect to the Retailers' § 1 Sherman Act claim under the rule of reason (Count 2), and Retailers' § 2 Sherman Act claims (Count 3), but GRANTING the Motion with respect to Retailers' claims of a per se violation under § 1 (Count 1) and their request for injunctive relief.

Finally, this Report recommends the court GRANT IN PART and DENY IN PART Defendants' Motion to Dismiss the EPPs' claims, (ECF No. 162). The court should GRANT the Motion with respect to all claims asserted under the laws of Alaska, Arkansas, Colorado, Connecticut, Idaho, Maryland, Massachusetts, Missouri, Montana and South Carolina. With respect to the claims asserted under the laws of the remaining thirty jurisdictions, this Report's recommended dispositions are summarized in the attached Exhibit A. The state law claims remaining in those jurisdictions, should the court adopt the recommendation, are set forth on the attached Exhibit B.

Review Procedure

By copy of this Report and recommendation, the parties are notified that pursuant to 28 U.S.C. § 636(b)(1)(C):

1. Any party may serve upon the other party and file with the Clerk written objections to the foregoing findings and recommendations within fourteen (14) days from the date of service of this Report on the objecting party, see 28 U.S.C. § 636(b)(1), computed pursuant to Rule 6 (a) of the Federal Rules of Civil Procedure. A party may respond to any other party's objections within fourteen (14) days after being served with a copy thereof. See Fed. R. Civ. P. 72(b)(2) (also computed pursuant to Rule 6(a) of the Federal Rules of Civil Procedure).

2. A district judge shall make a de novo determination of those portions of this Report or specified findings or recommendations to which objection is made.

The parties are further notified that failure to file timely objections to the findings and recommendations set forth above will result in a waiver of appeal from a judgment of this Court based on such findings and recommendations. Thomas v. Arn, 474 U.S. 140 (1985); Carr v. Hutto, 737 F.2d 433 (4th Cir. 1984); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER,
UNITED STATES MAGISTRATE JUDGE

February 6, 2019

EXHIBIT A -- In re Zetia (Ezetimibe) Antitrust Litig., MDL No. 2:18-md-2836

Summary of Recommended Dispositions of End-Payor Plaintiff Claims			
Jurisdiction	**Antitrust**	**Consumer Protection**	**Unjust Enrichment**
Alabama	NO CLAIM	NO CLAIM	SUSTAIN
Alaska	NO CLAIM	NO CLAIM	DISMISS
Arizona	SUSTAIN	SUSTAIN	SUSTAIN
Arkansas	NO CLAIM	DISMISS	DISMISS
California	DISMISS § 17200 ONLY	SUSTAIN	SUSTAIN
Colorado	NO CLAIM	NO CLAIM	DISMISS
Connecticut	NO CLAIM	NO CLAIM	DISMISS
District of Columbia	SUSTAIN	DISMISS	SUSTAIN
Florida	NO CLAIM	SUSTAIN	DISMISS
Hawaii	SUSTAIN	SUSTAIN	SUSTAIN
Idaho	NO CLAIM	DISMISS	DISMISS
Illinois	SUSTAIN	SUSTAIN	SUSTAIN
Iowa	SUSTAIN	NO CLAIM	SUSTAIN
Kansas	SUSTAIN	DISMISS	SUSTAIN
Maine	SUSTAIN	DISMISS	SUSTAIN
Maryland	NO CLAIM	NO CLAIM	DISMISS
Massachusetts	NO CLAIM	DISMISS	DISMISS
Michigan	SUSTAIN	DISMISS	DISMISS
Minnesota	SUSTAIN	DISMISS	SUSTAIN
Mississippi	SUSTAIN	NO CLAIM	SUSTAIN
Missouri	NO CLAIM	DISMISS	DISMISS
Montana	NO CLAIM	NO CLAIM	DISMISS
Nebraska	SUSTAIN	SUSTAIN	SUSTAIN
Nevada	SUSTAIN	SUSTAIN	SUSTAIN
New Hampshire	SUSTAIN	SUSTAIN	SUSTAIN
New Mexico	SUSTAIN	SUSTAIN	SUSTAIN
New York	SUSTAIN	DISMISS	SUSTAIN
North Carolina	SUSTAIN	SUSTAIN	SUSTAIN
North Dakota	SUSTAIN	NO CLAIM	SUSTAIN
Oregon	SUSTAIN	DISMISS	SUSTAIN
Puerto Rico	SUSTAIN	NO CLAIM	NO CLAIM
Rhode Island	SUSTAIN	DISMISS	SUSTAIN
South Carolina	NO CLAIM	NO CLAIM	DISMISS
South Dakota	SUSTAIN	DISMISS	SUSTAIN
Tennessee	SUSTAIN	DISMISS	SUSTAIN
Utah	SUSTAIN	DISMISS	SUSTAIN
Vermont	NO CLAIM	DISMISS	SUSTAIN
Virginia	NO CLAIM	SUSTAIN	NO CLAIM
West Virginia	SUSTAIN	SUSTAIN	SUSTAIN
Wisconsin	SUSTAIN	NO CLAIM	SUSTAIN

"SUSTAIN" means this Report recommends DENYING Defendants' motion to dismiss that claim.

"DISMISS" means this Report recommends GRANTING Defendants' motion to dismiss that claim.

"NO CLAIM" means Plaintiffs are not asserting that type of claim in the jurisdiction.

EXHIBIT B -- In re Zetia (Ezetimibe) Antitrust Litig., MDL No. 2:18-md-2836

The following table lists the jurisdictions in which this Report recommends GRANTING Defendants' Motion to Dismiss as to ALL EPP claims:
Alaska
Arkansas
Colorado
Connecticut
Idaho
Maryland
Massachusetts
Missouri
Montana
South Carolina

The following table lists all of the EPPs' claims (by jurisdiction) as to which this Report recommends DENYING Defendants' Motion to Dismiss:			
Alabama			Unjust Enrichment
Arizona	Antitrust	Consumer Protection	Unjust Enrichment
California	Antitrust(*)	Consumer Protection	Unjust Enrichment
District of Columbia	Antitrust		Unjust Enrichment
Florida		Consumer Protection	
Hawaii	Antitrust	Consumer Protection	Unjust Enrichment
Illinois	Antitrust	Consumer Protection	Unjust Enrichment
Iowa	Antitrust		Unjust Enrichment
Kansas	Antitrust		Unjust Enrichment
Maine	Antitrust		Unjust Enrichment
Michigan	Antitrust		
Minnesota	Antitrust		Unjust Enrichment
Mississippi	Antitrust		Unjust Enrichment
Nebraska	Antitrust	Consumer Protection	Unjust Enrichment
Nevada	Antitrust	Consumer Protection	Unjust Enrichment
New Hampshire	Antitrust	Consumer Protection	Unjust Enrichment
New Mexico	Antitrust	Consumer Protection	Unjust Enrichment
New York	Antitrust		Unjust Enrichment
North Carolina	Antitrust	Consumer Protection	Unjust Enrichment
North Dakota	Antitrust		Unjust Enrichment
Oregon	Antitrust		Unjust Enrichment
Puerto Rico	Antitrust		
Rhode Island	Antitrust		Unjust Enrichment
South Dakota	Antitrust		Unjust Enrichment
Tennessee	Antitrust		Unjust Enrichment
Utah	Antitrust		Unjust Enrichment
Vermont			Unjust Enrichment
Virginia		Consumer Protection	
West Virginia	Antitrust	Consumer Protection	Unjust Enrichment
Wisconsin	Antitrust		Unjust Enrichment

(*) The EPPs' monopolization claim under Cal. Bus. & Prof. Code § 17200 should be DISMISSED.